

Screening for Infectious Diseases Among Substance Abusers

Treatment Improvement Protocol (TIP) Series 6

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Care has been taken to make the information in this Treatment Improvement Protocol current. However, the user of this document should realize that regimens for treating infectious diseases do change, especially in the treatment of HIV/AIDS and multidrug-resistant tuberculosis. If there is any question about the appropriateness of any information contained in this protocol, or question about whether the information is current with the latest advances in treatment, the reader is encouraged to consult a specialist in infectious diseases.

What Is a TIP?

CSAT Treatment Improvement Protocols (TIPs) are prepared by the Quality Assurance and Evaluation Branch to facilitate the transfer of state-of-the-art protocols and guidelines for the treatment of alcohol and other drug (AOD) abuse from acknowledged clinical, research, and administrative experts to the Nation's AOD abuse treatment resources.

The dissemination of a TIP is the last step in a process that begins with the recommendation of an AOD abuse problem area for consideration by a panel of experts. These include clinicians, researchers, and program managers, as well as professionals in such related fields as social services or criminal justice.

Once a topic has been selected, CSAT creates a Federal Resource Panel, with members from pertinent Federal agencies and national organizations, to review the state of the art in treatment and program management in the area selected. Recommendations from this Federal Panel are then transmitted to the members of a second group, which consists of non-Federal experts who are intimately familiar with the topic. This group, known as a non-Federal Consensus Panel, meets for about three days, makes recommendations, defines protocols, and arrives at agreement on protocols. Its members represent AOD abuse treatment programs, hospitals, community health centers, counseling programs, criminal justice and child welfare agencies, and private practitioners. A Chair for the Panel is charged with responsibility for ensuring that the resulting protocol reflects true group consensus.

The next step is a review of the proposed guidelines and protocol by a third group whose members serve as expert field reviewers. Once their recommendations and responses have been reviewed, the Chair approves the document for publication. The result is a TIP reflecting the actual state of the art of AOD abuse treatment in public and private programs recognized for their provision of high-quality and innovative AOD abuse treatment.

This TIP on guidelines to screening for infectious diseases among substance abusers is the sixth published by CSAT since a treatment improvement initiative began. It represents another step by CSAT toward its goal of bringing national leadership to bear in the effort to improve AOD abuse treatment.

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Foreword

The Treatment Improvement Protocol Series (TIPs) fulfills CSAT's mission to improve alcohol and other drug (AOD) abuse and dependency treatment by providing best practices guidance to clinicians, program administrators, and payers. This guidance, in the form of a protocol, results from a careful consideration of all relevant clinical and health services research findings, demonstration experience, and implementation requirements. A panel of non-Federal clinical researchers, clinicians, program administrators, and patient advocates employs a consensus process to produce the product. This panel's work is reviewed and critiqued by field reviewers as it evolves.

The talent, dedication, and hard work that TIPs panelists and reviewers bring to this highly participatory process have bridged the gap between the promise of research and the needs of practicing clinicians and administrators. We are grateful to all who have joined with us to contribute to advance our substance abuse treatment field.

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Definition of the Term "Drug Use"

The term "drug use" as used in this Treatment Improvement Protocol (TIP) encompasses the following categories of drugs:

- Cannabis (marijuana, hashish)
- Cocaine
- Hallucinogens (e.g., LSD, mescaline)

- Inhalants (e.g., gasoline, glue)
- Alcohol
- Opioids (e.g., heroin, pentazocine [Talwin], codeine)
- Phencyclidine (PCP)
- Sedatives, hypnotics, or anxiolytics (e.g., barbiturates, benzodiazepines)
- Stimulants (e.g., amphetamines)

Tobacco, considered to be a drug, is excluded from this discussion because it is only marginally relevant to the topic of this TIP.

Chapter 1 - Introduction

Infectious diseases are common among drug users. Throughout the past decade, drug use and the frequency of infectious diseases among this population have escalated. The acquired immunodeficiency syndrome (AIDS) epidemic and the resurgence of tuberculosis have magnified the need for the prompt recognition and treatment of these and other infectious diseases.

Individuals who are dependent on drugs are represented disproportionately in the population with human immunodeficiency virus (HIV) and AIDS; tuberculosis, including multidrug-resistant tuberculosis; syphilis; and hepatitis B and C. Patients who enter drug treatment programs are at risk of having one or more of these diseases. This TIP focuses on these particular infectious diseases because they occur frequently among treatment populations and have significant medical and socioeconomic consequences for infected persons and others if not recognized and treated. In addition, the trained staff of a drug treatment program can screen for and medically manage these diseases.

Included in this TIP are discussions of other infectious diseases common to treatment populations, including chlamydia, gonorrhea, herpes simplex, chancroid, and hepatitis A and D. Information is provided about transmission, symptoms, and indications for screening. The TIP is intended for use in a broad variety of clinical settings - inpatient, residential rehabilitation, and outpatient facilities, including methadone and drug-free modalities. The TIP is intended for a wide audience: It is for use by all who come in contact with people who use drugs.

This TIP focuses on infectious diseases that are prevalent in and especially harmful to patients in drug treatment, and that can be medically managed by treatment staff or through referrals for primary care. The treatment recommendations in this TIP are largely, but not exclusively, based on guidelines from the Centers for Disease Control and Prevention (CDC). Trained medical staff are needed to diagnose and treat these diseases. Treatment providers who do not offer such medical resources are encouraged to refer their patients to community-based health care professionals. Followup care of those patients referred initially to other health care professionals should be provided.

Infectious Diseases Linked With Drug Use

Using drugs is an important risk factor for disease. Drug use is associated with such risk behaviors as the sharing of contaminated needles and other drug paraphernalia, and unsafe sexual practices that contribute to transmission of certain infectious diseases.

For example, research indicates

- There has been a steady increase in the incidence of hepatitis B, despite the availability of a vaccine since 1982. Most of the increase is attributed to injection drug use ([CDC 1988](#)). The prevalence of hepatitis C in injection drug users is also high ([Donahue 1991](#)).

- Injection drug use is closely linked to the spread of HIV. Patients infected with HIV, because of their impaired immune systems, are at increased risk of developing numerous infections, the majority of which represent reactivation of prior infection. However, HIV-infected persons are far more likely to develop active TB after exposure to TB than HIV-negative persons.
- An increase in cases of tuberculosis appears to be related to HIV infection and is seen primarily in the 25- to 44-age group. Multidrug-resistant tuberculosis has been detected in a growing number of States and is seen especially in large cities with high rates of drug use, homelessness, and HIV infection.
- The association between syphilis and drug use has been substantiated by retrospective studies and is particularly strong among cocaine users ([Haverkos 1990](#)).

Other Infectious Diseases Common in Treatment Populations

Persons enrolled in drug treatment programs are vulnerable to a range of debilitating diseases in addition to those that are the focus of this TIP. Detection and treatment of the following diseases should not be overlooked by treatment providers, although their prevalence will vary by risk behavior and, for some infections, by geographic area:

- *Endocarditis* - an infection of the heart valves by certain bacterial and fungal organisms. Immediate medical evaluation, including laboratory tests as indicated, and treatment of patients who exhibit persistent, unexplained fever are crucial to prevent further damage to the heart and other organs, or death. Persons with pre-existing valvular heart disease are at increased risk for developing endocarditis. Among drug users, endocarditis occurs primarily in persons who inject drugs. In most cases, the skin is the source of the infecting organism, but contamination of the injected drug and the drug paraphernalia may also be the source of the infection.
- *Bacteremia/septicemia* - bacterial invasion of the bloodstream that may result from use or sharing of contaminated needles and other drug paraphernalia. Patients exhibiting persistent fever should be medically evaluated and tested as indicated. Hospitalization and treatment with intravenous antibiotics and other appropriate supportive care are required.
- *Fungal infections* - such infections, including candidiasis and histoplasmosis, which can be relatively harmless in patients with normal immune systems, are persistent infections in HIV-infected patients. Cryptococcus and histoplasmosis may be life-threatening for AIDS patients, while Candida is rarely life-threatening. Medical evaluation and testing of patients with persistent fever, unusual skin problems, headache, or other systemic complaints are necessary.
- *Body lice/scabies* - have long been a concern of drug treatment providers, because an undetected case of body lice or scabies could spread to the treatment population. Disinfection of the patient and the patient's clothing and bedding is indicated. The occurrence of one case should trigger an investigation to see if there are additional cases among other patients that require treatment.
- *Venereal warts* - may occur among sexually active treatment program populations. Venereal warts are caused by DNA viruses and are most typically manifested as fleshy growths in the genital and rectal areas. Venereal warts are frequently more severe and less responsive to treatment in HIV-infected persons. Persons with venereal warts should be screened for syphilis because condyloma lata, which may be confused with viral warts, may occur in secondary syphilis. Venereal warts may be treated topically with cryotherapy or may require surgical excision.

Special Problems of Sexually Transmitted Diseases in Younger People and Women

Sexually transmitted diseases other than AIDS have the greatest impact on younger people under the age of 25, especially teenagers, and women. The Guttmacher Institute reports that one in five persons in the United States - 56 million people - have a viral sexually transmitted disease (such as genital herpes, human papillomavirus). Women account for about half of all sexually transmitted infections that occur each year, but they suffer more frequent and severe long-term consequences than men.

Sexually transmitted diseases (STDs) affect women disproportionately, because women tend to show fewer symptoms and as a consequence they go untreated for longer periods of time. A bacterial STD can usually be

cured if treated early. However, these diseases are often undetected. Many of the most serious problems from STDs come from undetected chlamydia and gonorrhea; many of these cases lead to bacterial infection of the uterus, fallopian tubes, or lining of the pelvic organs, sometimes causing infertility. The transmission of an STD to an unborn child or during childbirth can have devastating effects ([Guttmacher Institute 1993](#)).

Infectious Disease Screening and Drug Treatment

Many drug users are reluctant to become involved with traditional medical providers because of previous poor treatment and insensitive care. As a result, they may not seek testing for and treatment of infectious diseases. In addition, lack of access to health care, either because of financial or other socioeconomic reasons, may mean that drug users may have had minimal or no medical care before enrolling in a treatment program.

Drug treatment providers are ideally situated to reach out to their patient populations and provide infectious disease screening, medical services, and preventive counseling. Program staff have a good understanding of the lifestyles of individuals who use drugs and are sensitive to and knowledgeable about their concerns and needs.

Screening for infectious diseases in patients may be especially important to their recovery effort, may result in improved health and improved treatment compliance, and may prevent the spread of debilitating and life-threatening infectious diseases. Integration of drug treatment and infectious disease screening offers an important therapeutic intervention for patients, their families, and the broader community.

Guidelines for Infectious Disease Screening

All patients in treatment should have access to infectious disease screening, risk-reduction education and counseling, and therapeutic medical services. To provide these services, treatment programs are encouraged to develop appropriate procedures and identify local resources.

Upon entering treatment and periodically thereafter, patients should receive an assessment, physical examination, serologic and other laboratory screening, TB screening, counseling, and followup medical care as appropriate. Clinicians in treatment programs must be suitably trained to provide medical testing and care for patients with infectious diseases. Program administrators should strive for access to laboratory facilities, hospitals, community-based primary health care programs, and public health agencies if necessary services cannot be provided on site by the treatment programs.

Strategies for infectious disease screening and related services should reflect local conditions. Local epidemiological data can be helpful in identifying trends in the prevalence of particular diseases and in developing screening and counseling priorities. Essential referral networks established with local public health and other resources can serve the needs of the treatment population.

Data from treatment programs on the incidence and prevalence of infectious diseases among patient populations support surveillance efforts that are the basis for developing broadly based, effective public health policies and services.

An important source of epidemiological information and support for treatment providers is each State's public health contacts for infectious diseases. They can assist and collaborate with drug treatment staff to establish and maintain effective infectious disease screening programs.

The Consensus Development Process

The Center for Substance Abuse Treatment (CSAT) has sponsored the development of Treatment Improvement Protocols (TIPs) to provide guidance for the care of patients in drug treatment. The TIP development process was modeled on similar efforts undertaken by the Federal Government to address

complex health and social service delivery issues. The consensus model that was used to develop these guidelines drew on the experience and expertise of representative specialists from across the Nation.

The process began with CSAT's appointment of a Federal Resource Panel of medical personnel, drug treatment experts, social service providers, and representatives of national organizations. The Federal Panel established the overall scope and direction for the subsequent work of a Consensus Panel of experts charged with preparing guidelines covering medical screening and the treatment of infectious diseases.

The members of the Consensus Panel worked together in teams to prepare these screening and service guidelines. The draft guidelines were reviewed by additional field specialists. The final recommendations of the Consensus Panel reflect the diversity of experience and, most importantly, the agreement of many of the Nation's foremost experts as to the basic principles and guidelines for programs that should be used to provide screening and supportive care needed by patients in drug treatment.

Recommendations of the Consensus Panel

These guidelines are intended to provide direction for the many disciplines involved in drug treatment, including physicians, physician's assistants, nurses, nurse practitioners, social workers, psychologists, counselors, and other health and social service providers. They are designed to improve the screening of patients and staff for infectious diseases; to improve treatment for these diseases through better coordination of drug treatment programs, primary health care facilities, public health agencies, and infectious disease programs; and to reduce the incidence and consequences of these diseases by changing or modifying behavior. The guidelines may be used in a variety of settings, including inpatient, outpatient, and hospital-based drug treatment programs.

The Consensus Panel supports these key recommendations:

- Screening and counseling for HIV, tuberculosis, multidrug-resistant tuberculosis, hepatitis B and C, syphilis, and other infectious diseases, if indicated, that are prevalent in treatment populations should be offered to patients upon entry into treatment.
- Appropriate medical care is essential for infected patients.
- Patients have the right to refuse to be tested for infectious diseases and should not be denied treatment services based solely on that refusal, except where there is a potential public health threat to other patients or treatment staff. Treatment providers must evaluate the potential exposure risk for other patients and treatment staff, particularly for potential exposure to infectious tuberculosis. In all instances, patients should be educated about the benefits to themselves and others from proper and early diagnosis and treatment of infectious diseases.
- Pre- and post-test counseling services are needed to assist patients in preparing for and completing infectious disease screening and treatment, especially with reference to HIV.
- Risk reduction education and counseling interventions are vital to the prevention of infectious diseases. These interventions must be sensitive to and appropriate for the cultural and religious background of patients in treatment.
- Treatment program staff must be knowledgeable about and adhere to Federal and State confidentiality laws and regulations.
- Patients should be encouraged to provide information for contact tracing and partner notification.
- Treatment staff should be screened and treated as appropriate for tuberculosis. Screening should also be done for hepatitis B, with vaccination for those not previously vaccinated for or infected with hepatitis B.

The Consensus Panel encourages drug treatment staff and other service providers to use these guidelines to identify and coordinate their roles in the care of patients in treatment and after discharge.

Using These Guidelines

This TIP is intended to guide and instruct a broad spectrum of treatment and other health and public health care providers caring for drug treatment patients who are at risk for infectious diseases. Some of the guidelines provide information for specific disciplines such as counselors and physicians or other medical staff. Other parts, such as the legal and ethical guidelines, are pertinent to all service providers. A review of the entire TIP will help providers create and maintain the continuum of care that is vital to the well-being and recovery of their patients.

The first part of this TIP addresses issues that affect and support the entire infectious disease screening and treatment process. The remaining chapters provide protocols for specific infectious diseases that are common in treatment populations. The protocols include information on prevalence and disease symptoms, screening procedures, and treatment regimens.

Some chapters include a list of sources. The vast majority of information presented in this TIP is not referenced, however, because it was developed through a consensus process and is the unique product of the experience and expertise of Panel members.

- "Issues for Counselors" presents a discussion of counseling issues relevant to infectious disease screening for treatment populations. The chapter reviews the critical role of the counselor in providing pre- and post-test counseling and risk reduction interventions.
- "Legal and Ethical Issues" provides a discussion of legal and ethical issues such as confidentiality, recordkeeping, reporting, and the duty to warn.
- "Issues for Treatment Program Administrators" offers guidance for treatment program administrators concerning staff training and community development issues and environmental safety.
- "The Initial Patient Contact" discusses establishing a therapeutic relationship, assessing risk, and issues pertaining to taking a history.
- Protocols for the screening and treatment of tuberculosis and multidrug-resistant tuberculosis are presented.
- HIV/AIDS screening and referrals for continuing medical management are discussed.
- Hepatitis B, C, A, and D are discussed.
- The sexually transmitted diseases syphilis, gonorrhea, chlamydia, herpes simplex, and chancroid are discussed.

A variety of other sexually transmitted diseases, prevalent in treatment populations including many that are common to women, are not addressed in this TIP. For more information, the reader is referred to the Centers for Disease Control, *Sexually Transmitted Diseases: Clinical Practice Guidelines*.

The TIP also includes several appendixes that were developed outside the Consensus Panel process.

- [Appendix A](#) consists of a bibliography of references that can provide additional information for treatment providers.
- [Appendix B](#) identifies participants in the CSAT Federal Resource Panel.
- [Appendix C](#) lists field reviewers of this TIP.
- [Appendix D](#) is a resource list.
- [Appendix E](#) presents models for State drug agencies and local treatment programs to use in estimating the costs of implementing screening guidelines for infectious diseases. The models include recommendations for specific services and staffing patterns to create or enhance existing screening services.
- [Appendix F](#) discusses quality assurance.
- [Appendix G](#) is an HIV/AIDS Prevention Bulletin from the Centers for Disease Control and Prevention, the Center for Substance Abuse Treatment, and the National Institute on Drug Abuse. The bulletin, dated April 19, 1993, discusses the limitations of bleach in eradicating or inactivating HIV in injection equipment. The bulletin lists updated bleach recommendations as well as other disinfection methods for injection equipment.

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Chapter 2 - Issues for Counselors

Research indicates that drug use increases an individual's risk of contracting a number of infectious diseases, or leads to behaviors that increase that risk. The incidence and prevalence of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), tuberculosis, hepatitis B, syphilis and other sexually transmitted diseases (STDs), in addition to other medical conditions, is high in persons enrolled in drug

treatment programs. Integrating screening for infectious diseases with drug treatment is an important response to the growing public health concern about these high rates of infection, and of HIV in particular.

Screening for infectious diseases in the treatment setting requires not only medical management but supportive counseling. Beyond the direct physical effects of disease, a number of psychosocial problems may be present and need to be addressed.

The counselor in a drug treatment setting can play a key role in assessing risk, providing pre- and post-test counseling, facilitating contact tracing and partner notification, implementing risk reduction and retention in treatment strategies, and interfacing with medical, public health, and other agencies. Training that improves awareness of infectious disease issues can provide counselors and other treatment staff with needed skills for improved patient care.

The Critical Role of the Counselor

The drug treatment counselor is trained to assist patients to enter, participate in, and complete a treatment program. It is the counselor who typically prepares or participates in preparing the treatment plan and monitors patient progress toward treatment goals. Services offered by the counselor may include individual, group, and family counseling, as well as followup case management.

To these well-established functions, the counselor is encouraged to add the following services that support the screening of patients for infectious diseases.

- *Assess patient risk factors.* A complete history is needed if medical and treatment staff are to adequately assess the patient's risk for infectious disease. During the initial intake or assessment interview with the patient, the counselor can help solicit sensitive drug-taking and sexual practice information (see "The Initial Patient Contact").
- *Provide pre- and post-test counseling.* Counseling is especially critical prior to and following HIV-antibody testing. Patients may relapse or drop out of treatment entirely when considering testing or immediately after testing. Positive test results are frequently devastating to patients and their families. Counselors should be alert to the concerns and vulnerability of patients during this time. Counseling and referral assistance may be especially helpful for those previously known to be infected or for those whose test results are positive while in treatment.
- *Provide and follow up patient referrals.* Patients infected with certain diseases after the initial screening will require medical care. If medical care is offered by the treatment program, the counselor can arrange for this care. When patients must be referred to other sources of medical care, such as a hospital or STD clinic, the counselor should act as the patient's advocate in arranging for treatment and tracking followup care with the medical facility. In addition to coordinating the care of the patient and acting as the patient's advocate, the counselor can encourage the patient to complete prescribed therapy.
- *Conduct and support risk reduction and treatment retention interventions.* These interventions are essential components of the patient's treatment plan and should be designed with the needs and goals of the patient in mind. The counselor can deliver or provide for the delivery of education, counseling, and other support services that reduce the patient's risk of contracting or transmitting infectious diseases.
- *Facilitate contact tracing and partner notifications.* Patients who have evidence of certain infectious diseases after the initial screening should be encouraged to identify and, when possible and advisable, inform sexual and drug-using partners or others of their risk for infection due to exposure to the patient. The counselor should support and encourage the patient during this process.
- *Participate in staff development activities.* Treating individuals who use drugs continues to be challenging and rewarding work. However, the increase in the incidence of infectious diseases, and HIV/AIDS in particular, has intensified the emotional impact of the treatment process for many staff members, including counseling professionals. Awareness training, skills development, and supportive group activities give counselors opportunities to enhance their professional abilities and improve services to patients. In addition, all staff should take part in the treatment program's regular infection

control and prevention efforts (see "Issues for Treatment Program Administrators: Staff and Community Development and Environmental Safety").

- *Participate in and support community-based interventions.* The effectiveness of a treatment program is enhanced by well-developed links with other service organizations. In addition to providing direct services to patients and their families, the counselor can inform other service providers about drug use and infectious diseases, and participate on behalf of the treatment program in the community's service delivery network (see "Issues for Treatment Program Administrators").

Assessing Risk for Infection

Proper identification of infected persons is the first line of defense in limiting the spread of infectious diseases. A major hindrance to public health efforts to prevent infectious diseases is the inability or failure to identify cases among drug users and to adequately treat them and their contacts.

The drug treatment setting is an ideal place to identify individuals with infectious disease problems and to initiate and maintain appropriate management. Many treatment programs need to have a clear understanding of their patients' risk status.

As individuals enter treatment, a careful assessment of their risk for infectious disease is essential (see "The Initial Patient Contact"). The counselor should be alert to the presence of

- *Injection drug use.* Injection drug users are at particularly high risk for HIV disease, hepatitis B, and sexually transmitted diseases because of unsafe sexual and risky drug-taking practices, including frequent needle sharing. Injection drug users who are HIV positive are also more likely to develop infectious tuberculosis than those not infected with HIV.
- *Sexual partners of injection drug users.* Sexual partners of injection drug users, predominantly women, are at high risk for HIV, hepatitis B, and sexually transmitted diseases. In some cases, these individuals may not realize that their partner's drug use places them at risk for infection. Many of these women may use other, noninjectable drugs. Their own drug use can lead to unsafe sexual practices that increase their risk of infection.
- *Unprotected sexual contacts.* Drug users who do not practice safer sex increase their risk for HIV and other sexually transmitted diseases. Especially high-risk sexual practices are the failure to use or the improper use of condoms, and contact that involves anal penetration.
- *Multiple sex partners.* Having multiple sex partners increases the risk of hepatitis B, HIV, and sexually transmitted diseases. The practice of providing sex for drugs, money, or shelter is associated with a higher risk of infection.
- *Poor urban dwellers.* Poor urban dwellers who have substandard housing and lack access to good medical care are vulnerable to many diseases. Tuberculosis, which is spread by airborne infectious particles, occurs with the greatest frequency in crowded urban areas.
- *Homelessness.* Poor hygiene, inadequate nutrition and medical care, chronic drug use, crowded shelters, and unsanitary living conditions contribute to the incidence of infectious diseases among the homeless. Homeless youth have high rates of drug use and sexual risk-taking behaviors, placing them at particularly high risk for HIV infection.
- *History of incarceration and institutionalization.* Having been imprisoned or having been a resident in an institutional setting increases the likelihood of having been exposed to HIV, tuberculosis, and hepatitis. Lower socioeconomic status. Research has repeatedly demonstrated strong associations between ill health, including infectious diseases, and lower income. Individuals with lower incomes have poor access to health care and to risk reduction information. Support for the implementation of risk reduction strategies is frequently not available.
- *Disease history.* Repeated infection with sexually transmitted diseases is associated with increased risk for HIV infection. A history of recurrent sexually transmitted diseases, reactive tuberculosis skin test or diagnosed active tuberculosis, or dermatomal herpes zoster should all raise the level of suspicion at the treatment setting that the person may be HIV infected.

Infectious Disease Testing

Drug use can place patients at increased risk for infectious diseases. The Centers for Disease Control and Prevention (CDC) recommends that treatment programs screen all patients for tuberculosis (CDC n.d.) and all injection drug users for the human immunodeficiency virus (HIV) (CDC 1987). For methadone programs, Federal regulations presently require that all patients have a serologic test for syphilis as well as a tuberculin skin test on entry and annually thereafter.¹

An initial medical history and physical examination on admission to treatment will help determine the need for and advisability of testing and treatment for other infectious diseases.

Preparation for Testing

The counselor has an important role in preparing patients for testing and in providing or arranging for supportive counseling and case management following testing. The counselor should

- *Create an environment that conveys trust and acceptance, encourages communication, and validates feelings.* Establish a positive and open relationship with patients to help them express, discuss, and overcome any barriers to involvement with the health care system.
- *Discuss the process of testing, test procedures, possible outcomes, and treatment resources.* Entry into drug treatment presents an opportunity for the patient to focus on health matters and to take time to seek diagnosis and treatment for medical concerns.
- *Explain confidentiality procedures and reporting requirements.* Patients may be unaware of their rights to confidentiality and how contact tracing and/or partner notification impinge on this protection.
- *Discuss infection containment and risk reduction strategies.* Educational instruction on how the various infectious diseases are transmitted and on methods to reduce the potential of transmission to family contacts is helpful for the patient. The patient should be told how soon the infection responds to therapy to eliminate transmission and told about precautions that can be employed until the infection has been eliminated or controlled. If the infection is chronic and communicable, the patient needs information on how to protect the health of close contacts. Patients need to be advised on how to protect themselves from reinfection or a new infection.
- *Discuss retesting.* Retesting may be indicated when there is suspicion about a false-positive or false-negative result, when the indication for testing is recurrent or ongoing, or to determine whether intervention has been successful in eliminating the causative agent of the infectious disease.
- *Discuss contact tracing and partner notification.* Patients need to be informed of instances in which contact tracing of close household contacts is required and when sexual partner notification follows a positive result of a test. This information is ideally made available prior to testing; the patient's reservations regarding involvement can be addressed with a counselor who has established a relationship with the patient. The counselor then can help the patient in accepting the assistance of health authorities in informing contacts and partners.
- *Assist the patient to make the best decision regarding obtaining medical care.* When an untreated infection poses a threat to self or others (for example, a patient suspected of having tuberculosis or untreated syphilis in a pregnant woman), immediate testing and treatment should be initiated. If the patient wants or needs to prioritize health concerns, support addressing those concerns that pose the most imminent danger (for example, alcohol withdrawal seizures before HIV testing). Fear of a test result is not a valid reason to delay diagnosis of a potentially life-threatening infection for which there is an available cure or way to lessen the severity and course of the infection.

Testing requires the participation of the patient, and in some cases can be done only with the informed consent of the patient.

Testing for HIV

The CDC recommends that all injection drug users be screened for HIV. Drug treatment providers also need to assess the risk of HIV in noninjection drug users who enter treatment and should work with the patient to

determine if HIV serologic testing is needed. Testing for HIV should be performed only with the consent of the patient. For persons being tested for HIV, pre- and post-test counseling is the standard of care. The counselor has an important role in preparing patients for testing and in providing or arranging for supportive counseling and case management following testing.

Drug treatment providers should be aware of the importance of pre- and post-test counseling and should ensure that counseling is available in the on-site program or that the basic elements of counseling are being offered by the referral provider.

Pre-Test Counseling

If testing is indicated, the counselor can prepare the patient in the following ways:

- *Create an environment that conveys trust and acceptance, encourages communication, and validates feelings.* When they enter treatment, patients may suspect that they are infected, they may have a high risk for infection, or they may be symptomatic. The counselor can establish a positive and open relationship with patients to help them overcome any fears they may have about testing and the testing process.
- *Discuss risk factors, modes of transmission, purpose of the test(s), test procedures, possible outcomes, and treatment.* To facilitate testing, and the patient's decision regarding testing, the counselor and the patient can discuss the patient's risk factors for infection, as well as the symptoms and modes of transmission of HIV.

The benefits of testing should be stressed. For example, testing may prevent serious health consequences, even death, for the patient, family members, and others in the community. Early diagnosis of disease provides an opportunity for the patient to obtain effective medical care that can prevent or delay serious illness. Testing also provides an opportunity for the patient to modify personal risk behaviors and reduce the possibility of subsequent infections.

Patients need information about the testing process and the specific tests that are used to diagnose and confirm HIV infection. The counselor can emphasize that the only way to diagnose HIV is to be tested. Information offered to patients may include a description of the test(s) that will be performed, the procedures involved, the location and hours of operation of testing facilities, and the qualifications and type of staff who perform the tests.

Patients may be particularly anxious about how and when test results will be provided. The counselor can discuss possible test outcomes, the usual length of time between testing and availability of results, reasons for possible retesting, and the importance of post-test counseling.

Patients should be reassured that medical treatment is available and can be effective. The counselor can explain that recovery and subsequent disease prevention depend on the patient's compliance with prescribed regimens.

- *Assess possible reactions to test results.* Patients may experience some distress while waiting for test results. Once received, test results can cause further distress, fear, anger, or denial. The counselor can assess the responses of patients to testing and provide referrals to mental health service providers, social service agencies, and others as appropriate.
- *Explain confidentiality procedures and reporting requirements.* Patients may be unaware of informed consent procedures, their rights to confidentiality, and the exceptions to these protections. The counselor can inform and assure patients that all testing is voluntary and that treatment services cannot be withheld if testing is refused. Consent should be obtained before any testing procedure takes place and is required for HIV testing in some jurisdictions.

HIV test results may be reportable (see "Legal and Ethical Issues"), and AIDS cases with patient identifiers must be reported to health authorities.

- *Discuss risk-reduction strategies.* Educational instruction on risk reduction behaviors provides patients, their sexual partners, and their family members with strategies to reduce the possible transmission of infection. The counselor can stress the importance of following these strategies whether or not patients test positive for HIV.
- *Discuss retesting.* Testing for HIV consists of an initial screening test and one or two additional confirmatory tests. This combination of tests is sensitive and specific.

In addition to immediate retesting in cases in which there is concern that the test results may be a false positive or false negative, retesting in several months may be appropriate for individual patients. HIV antibodies, for example, may not be detectable for up to 12 months or longer following infection. The counselor should urge patients to be retested if they have another potential exposure to the HIV virus, such as drug use, needle sharing, unsafe sexual practices, or sexual victimization. A more detailed discussion on retesting follows in the discussion on counseling the HIV-positive patient and in the screening section of "Human Immunodeficiency Virus and the Acquired Immunodeficiency Syndrome."

- *Discuss contact tracing and partner notification.* Patients need to be prepared to assist health authorities to inform their contacts and partners if test results are positive.

The counselor can encourage and support patients who test positive for HIV to notify contacts and partners of the implications of the test results and to bring partners in for testing or refer them to other sites for testing. At the request of the patient, health department personnel can be asked to assist in this notification process.

- *Support patient decisions on testing.* The patient may choose not to be tested for HIV the first time it is discussed. While the uncertainty of waiting for test results or positive indications of infection can be stressful and may threaten the patient's efforts to abstain from the use of drugs, this alone should not be viewed as a valid reason to delay testing. The counselor can acknowledge and convey an acceptance of the patient's decision regarding testing, but should continue to educate the patient about HIV and other infectious diseases, and encourage testing at a future date, the earlier the better.

Post-Test Counseling

The following discussion addresses post-test counseling issues, especially concerning positive outcomes. The issues of positive results for HIV that need addressing are so different from those associated with other infectious diseases that they are dealt with separately. These issues are addressed again in the [chapter on HIV and AIDS](#).

Because of the severe distress patients experience while waiting for test results, counselors are advised that they only have 10 to 60 seconds to communicate information that will be comprehended by their patients after their test result is reported to them. A second post-test session may be needed after the patient gets over the initial elation or depression of finding out test results.

Counseling the HIV-Positive Patient

Patients who are HIV positive need acceptance, information, medical care, and supportive counseling that allows for the expression of painful feelings and promotes the development of coping mechanisms. The counselor can assist patients in the following ways:

- *Explain the meaning of positive results.* Patients with a positive HIV test result have HIV infection and will develop AIDS. The progression of illness in individual patients is unpredictable, but proper medical care may significantly slow this process. The counselor should advise the patient that he or she is infectious and must follow precautions to prevent the transmission of the virus to others, especially via sexual contact or injection drug use.
- *Discuss the need for retesting to confirm initial test results.* Although HIV-antibody tests are extremely accurate when properly done, false-positive and false-negative results may occur and retesting may be advisable for some patients. Because false-positive results do occur, retesting is advisable for persons

who strongly deny any risk factors and are unwilling to accept an initial positive result. Retesting is also advisable for patients who are in a state of denial and need further evidence of a positive test. Although false-positive results may be found for one of the tests used to confirm that a patient is HIV-infected, the presence of a positive HIV EIA and a positive Western blot confirms HIV infection.

For a patient who may have been infected with HIV in the recent past (that is, 8 to 12 weeks ago), the HIV tests may be falsely negative because that patient is in the incubation period before seroconversion. For a person with known HIV risk factors, the HIV test should be repeated in 3 months and again in 6 to 12 months. As long as a patient engages in behavior associated with risk of exposure to HIV, that person should be retested every 3 to 6 months.

In the face of overwhelming evidence of an HIV- or AIDS-related infection and a negative test, the test should be repeated.

- *Refer the patient for medical care.* Even when there are no symptoms, monitoring for disease progression and the start of appropriate treatment may delay the development of AIDS.
- *Help the patient to decide whom to tell about the results.* It is important to encourage patients who test positive for HIV to inform their sexual and drug-using partners. Not only are these individuals at risk for infection, they may be already infected. Partners should be tested and referred to medical care and other supportive resources. The children of HIV-infected women must also be tested for HIV.

The counselor can assist patients in making decisions about informing family members, friends, and others of their HIV status and anticipating and preparing for the range of responses. As part of this process, the counselor and patient should carefully discuss the possibility of abuse by a spouse or sexual partner. Health department personnel may be helpful for these and other patients who do not choose to notify their sexual and drug-using partners.

- *Explore feelings about the disease.* After finding out that one is HIV infected, the responses may include intense anxiety; feelings of physical and social isolation; fear of death, illness, and discrimination; concern about loss of relationships and support systems; guilt and self-blame; a negative self-image; obsession with symptoms; anger; and depression.

The counselor can reassure patients that their feelings, including initial shock and denial, are understandable and normal. A drug-injecting user may feel guilty about infecting his drug-free sexual partner; parents may feel particular guilt if their child has been infected perinatally. Individual and group counseling can facilitate and encourage the expression of difficult feelings, including anger, guilt, and anxiety.

Patients also may need referral to other counseling resources in the community.

- *Discuss withdrawal and self-imposed isolation as reactions to disease.* Being HIV positive is associated with being viewed as someone who engages in high-risk sexual behavior and/or drug abuse. Patients are often faced with extreme isolation because of misunderstandings about modes of transmission. Patients may need assistance to maintain an existing network of friends and family or to develop such a support network.
- *Assess suicide potential and provide referral to mental health care.* Patients who are HIV positive may contemplate suicide at some point following their diagnosis, but most overcome these thoughts. The counselor should be aware that some patients may have higher rates of mood disorders. It is imperative that drug treatment programs have a well-defined protocol to respond to all suicidal thoughts or gestures.
- *Emphasize risk-reduction behaviors.* Safer sexual practices and abstinence from drugs are important risk-reduction behaviors. The counselor should constantly emphasize the importance of risk-reduction behaviors and their benefits.
- *Help the patient to set priorities and goals.* Patients who test positive for HIV are at high risk for a return to drug use. The counselor can emphasize the fact that abstinence is critical for maximum health and physical well-being. Drug use may further impair the immune system.

Resumption of and continued use of drugs place the patient at risk for needle sharing and unsafe sexual practices that may lead to exposure to infectious diseases. Of particular concern is the risk of infection with a different and potentially more virulent and resistant strain of HIV. Exposure to such a strain may hasten the progression of HIV to AIDS.

- *Support the patient in joining an HIV support group.* The patient who is HIV positive may benefit from the help and understanding provided by a community-based HIV support group. The counselor can provide information about such groups and encourage and facilitate attendance by patients and family members during treatment and after its completion.
- *Support the patient and family members in anticipatory mourning and expression of other feelings about this life-threatening infection.* Feelings of impending loss and grief can be frightening and may lead to the further debilitation and isolation of the patient. Patients need assurance that these feelings are a part of a healthy coping process.
- *Help the patient and family members recognize their own capacities and limitations.* Faced with a life-threatening disease, patients and their family members struggling to cope with feelings of loss may also confront employment, physical, and financial concerns. Counseling and referrals to community-based resources can provide the assistance needed to maintain a positive lifestyle.
- *Provide and follow up referrals to mental health, social service, and other community resources.* Following treatment for drug use, patients benefit from a comprehensive continuum of care. For patients who are also HIV positive, the following types of referrals may be of assistance: specialized medical care; mental health care, including medication management; financial assistance; housing; child care; and legal consultation.

Counseling the Patient With Positive Test Results for Other Infectious Diseases

Patients infected with tuberculosis, viral hepatitis, and syphilis or other sexually transmitted diseases also need emotional support and counseling. The counselor can assist these patients in the following ways:

- *Provide and follow up referrals for medical care.* Patients who test positive for infectious diseases need medical treatment. The counselor can prepare patients for specific treatment regimens by explaining and discussing the importance of following all procedures, keeping appointments for checkups, and taking medications. Anticipated treatment outcomes can be reviewed to assure patients of the efficacy of the medical plan and to allay concerns about any necessary procedures. Followup with patients is critically important to ensure that appointments are kept.
- *Discuss procedures for and implications of mandatory reporting of test results to health officials.* Patients need to be informed about the community's mandatory reporting requirements for positive test results. They should be thoroughly familiar with their right to confidentiality, while being aware of the need to inform health department infectious disease practitioners of all contacts and partners who may be at risk for infection. This reporting can be done without stating that the patient is in drug treatment.
- *Explore feelings about the disease.* Patients need to be well informed about the signs and symptoms of disease, routes of transmission, and short- and long-term effects. Some patients may be inappropriately unconcerned about infection, and others may have erroneous fears and anxieties about these infections.
- *Emphasize risk-reduction behavior.* Discuss safer sexual partners and abstinence from drugs as important risk-reduction behaviors. The counselor should constantly emphasize the importance of these behaviors and their benefits. For viral infections such as HIV and herpes simplex, for which there is no cure, prevention of transmission is the most effective approach.
- *Provide and follow up referrals to community resources.* The counselor can provide and follow up on referrals to medical care, social services, mental health care, and other community resources to assist patients in their recovery from drug use and to maintain risk-reduction behaviors.

Counseling the Patient With Negative Test Results

Patients need a careful explanation of the meaning of negative test results. In some cases, repeat tests may be needed on a regular basis. With many patients, a negative test result provides a nonthreatening window of opportunity for important education and counseling about protection from infectious disease. This window of

opportunity may be particularly important for adolescent drug users who might otherwise continue high-risk behaviors without being concerned about the possibility of being at risk for infection.

Risk-reduction education and counseling are needed by all patients who receive treatment. Patients who agree to be tested for an infectious disease and who test negative should be reminded about the need to change their high-risk behaviors so that they will not be exposed and infected.

Contact Tracing and Partner Notification

Contact tracing and partner notification are activities intended to interrupt the transmission of disease. Once positive test results are received, patients should be encouraged to provide the names and locations of sexual partners, injection drug-sharing partners, or contacts at risk for infection. The counselor may play an important role in notifying contacts of nonreportable infections. Contact tracing and partner notification are conducted by health department personnel for reportable diseases regardless of the wishes of the infected person.

In most jurisdictions, HIV test results are reported for epidemiological reasons but are reported without patient identifiers and no contact tracing is done. In some jurisdictions, a positive HIV test result is reportable and contact notification is required. In other jurisdictions, health department personnel, at the request of the patient, may assist in tracing and notifying contacts and partners of HIV-positive patients. Contacts who test HIV negative may be motivated to make and maintain changes in behavior to reduce their risk for infection in the future.

Throughout this informing process the counselor can assist and support patients in the following ways:

- *Discuss the processes of contact tracing and partner notification.* Health care providers must report specific infectious disease cases to health authorities. Subsequent contact tracing and partner notification are then conducted. Patients need to be fully informed of these requirements and assured that identifying information is kept confidential. The counselor can assist the patient to review current or past behaviors that may have placed others at risk for infection. The importance of full disclosure of the names and locations of potentially at-risk contacts and sexual and drug-using partners can be reinforced.
- *Assist the HIV-positive patient in reaching a decision to notify (or have notified) contacts and partners.* When the reporting of positive test results is not required by law, patients should be counseled about the benefits of contact and partner notification. For example, exposed persons can seek testing and early medical care; women who are pregnant can obtain reproductive counseling or appropriate prenatal care; high-risk sexual and drug-using behaviors can be modified or discontinued; and unhealthy environments can be improved or changed.

It is helpful for patients to have opportunities to discuss their fears about contact and partner notification. For example, patients may fear the loss of a relationship, physical violence, the loss of housing or other physical or emotional support, and the loss of confidentiality and misuse of the information.

When patients choose to notify contacts and partners, they may need assistance to develop effective ways to communicate with these individuals. Using such techniques as role playing, patients can be prepared for uncomfortable situations that might arise.

- *Discuss patient fears, feelings of embarrassment, and guilt.* Patients may be fearful about exposure and rejection by sexual partners, guilty over possible infection of others, and embarrassed about being infected, homeless, or other circumstances. Adolescents may be particularly embarrassed about their infection and continue their risk-taking behaviors. The counselor can discuss referral options to community-based services to address these needs, such as housing and financial assistance, peer support groups, and mental health care.
- *Explore the risk of violence, other abuse, loss of housing, or loss of emotional support.* Some women, particularly those with children, may fear abandonment and physical or emotional abuse from a partner if their test results are revealed. Some men may be afraid that their wives or partners will leave them.

The counselor can discuss referral options to community-based services to address needs such as legal intervention, housing assistance, child care services, and financial assistance.

- *Discuss confidentiality issues.* Patients may be fearful that contacts will be able to discern their identity and that confidential and sensitive information will be misused. Patients may be unwilling to provide information, or they may provide incorrect or incomplete contact and partner information. In some cases, when sex is exchanged for drugs or for money to buy drugs, partners are anonymous. The counselor can reassure patients concerning the confidentiality of treatment records and acknowledge the concerns that are expressed.

Risk Reduction

Many patients in treatment will be free of infectious diseases. Others may test positive for one or more diseases and need medical care and other services. Every patient should receive risk-reduction education and counseling. These efforts will help prevent future infection in patients who currently test negative for infectious diseases and reduce the risk to others from those patients who currently test positive for HIV and other infectious diseases.

Principles of Risk Reduction

The experiences of drug treatment programs suggest that the following broad principles guide counselor-based risk-reduction activities:

- Establish a warm and trusting relationship with the patient, based on mutual respect and regard.
- Incorporate risk-reduction approaches into the overall treatment program that emphasize the benefits of preventive health behaviors for a variety of health concerns.
- Provide risk-reduction education and counseling that is sensitive to the cultural values, religious beliefs, and traditions of the individuals being served, as well as the socioeconomic and day-to-day realities of their lives.
- Understand that it is fairly easy to change knowledge, more difficult to change attitudes, and extremely difficult to change behavior.
- Acknowledge that some risk-reduction programs will not work or will not work in the way it was assumed that they would work.
- Do not focus on scare tactics. Scare tactics are usually ineffective, especially when dealing with adolescents and young adults.
- Expect modest levels of change.

Risk-Reduction Strategies

The prevention of certain infectious diseases, such as HIV, tuberculosis, hepatitis B, and syphilis and other sexually transmitted diseases, requires that patients permanently alter their risk-associated behaviors, especially drug use and unsafe sexual practices. In addition, patients need to be aware of environmental risks for exposure to tuberculosis.

Risk-reduction strategies can be implemented in a variety of settings, including drug treatment programs, STD clinics, and other service facilities. These strategies can include group and individual sessions designed to provide information about risk factors, evaluate personal risk, overcome barriers to behavioral change, and develop skills. A combination of these strategies may be necessary to facilitate change by individuals in treatment. For example, the counselor may consider the following strategies:

- Provide patients with information about the relationship between drug use, particularly injection drug use, and the transmission of infectious diseases. Discuss with patients the likelihood of their having unprotected, high-risk sexual contact while under the influence of alcohol and other drugs.
- Provide patients with information about the various routes of infectious disease transmission, including unprotected sexual contact, sharing of contaminated needles and equipment, transmission from an

infected mother to her fetus or infant, and by exposure to airborne droplets containing the mycobacteria that cause tuberculosis. Review ways that patients can avoid or minimize exposure and infection, and the risks associated with repeated exposure to infection.

- Encourage participation in an HIV/AIDS self-help group for HIV-positive patients. These groups offer information and encourage and facilitate risk reduction behaviors, and are effective in relieving the isolation and stigmatization that still accompany HIV/AIDS.

Safer Sexual Practices

The initiation of safer sexual practices is a primary risk reduction strategy that can help protect patients from a variety of infectious diseases.

Other than sexual abstinence, the consistent and proper use of condoms is currently the most effective way to prevent HIV and other sexually transmitted diseases. Guidelines on how to use a condom are available and can be discussed with patients ([see table 1](#)). Condoms containing spermicides, especially nonoxynol-9, offer some additional protection against bacterial sexually transmitted diseases. Vaginal use of spermicides along with condoms is likely to provide still greater protection. Spermicides alone also offer some protection against sexually transmitted diseases. The following examples of counselor-based activities can also promote safer sexual behavior by patients.

- Educate patients about the risk of infection through unprotected sex, particularly with injection drug users and multiple partners.
- Discuss possible barriers to safer sexual practices and ways to overcome these barriers. Incorporate ethnic and cultural perspectives to circumvent barriers to the use of condoms.
- Provide materials that offer sex-positive messages, that make safer sex messages appealing to patients, and that link pleasurable sex with safer sex. Materials with these messages have been shown to increase favorable attitudes toward the use of condoms.
- Educate both women and men about the potential impact of infection on a developing fetus or on a newborn infant. The risk of HIV infection occurs through unprotected sexual activity with an infected partner. The risk of infection to either partner or the fetus remains throughout the pregnancy. Infection may occur at conception, but there is continued risk throughout the pregnancy. There is a need to use condoms for the barrier protection throughout pregnancy to prevent HIV infection of mother and unborn child.
- Recognize that sometimes there is an imbalance of power in a relationship; a patient may be reluctant to insist on safer sex practices, including barrier methods, out of fear of being battered. A counselor may need to explore the cultural and social norms of the patient and recognize whether these might have an impact on the patient's ability to recognize being at risk for abuse or ability to acknowledge verbal, sexual, or physical abuse. Assist women to assess and avoid possible domestic violence should they initiate unwelcome changes in sexual practices. Explore options for protective measures for these patients. Appropriate pre- and post-test counseling should be offered to all patients.
- Provide adolescent patients with information about the relationship among infectious diseases, drug use, and such risk-taking behaviors as the failure to use condoms; the exchange of sex for drugs, money, or shelter; and multiple sexual partners.

Retention in Treatment

Many studies and common clinical experience indicate that the longer patients stay in treatment, the better the patient outcome and the less likely patients are to experience negative sequelae of their drug use. Dependence on drugs is considered a chronic and relapsing disease. Relapse is the inability of patients to maintain abstinence from drugs and is one of the core features of addiction. Maintaining the patient in treatment long enough to establish abstinence and working with the patient through sometimes multiple episodes of drug use is the overall theme of treatment. It is never appropriate to discharge a patient solely on the basis of drug use while in treatment.

Preventing the patient's return to drug use is an important strategy for reducing the incidence of infectious diseases. Maintenance efforts are also needed to help patients who initiate safer sexual behaviors to maintain them. Return to high-risk sexual behaviors, as well as drug use, can expose the patient and others to infection.

For patients not in long-term therapy such as methadone maintenance or a long-term therapeutic community, a powerful intervention - some would say *the* most powerful intervention - is to teach the patient during the time that he or she is in treatment how to access health care. Competent health utilization skills include the patient's knowing who the local health care provider is and how to get there. The counselor should work out insurance benefits with the patient, and if the patient is not eligible for insurance, that patient should know how to get care for medical emergencies. The patient should be in the habit of accessing care and making return visits. The patient should also know how and where to reenter the drug treatment system. During treatment, information should be provided about community-based programs that deal with ongoing recovery needs. These self-advocacy skills will serve the patient well once he or she is no longer in a treatment program.

The following are examples of counselor-based activities that can support the patient in treatment and reduce the possibility of a return to drug use:

- Develop a positive and trusting relationship with the patient to encourage retention in treatment.
- Encourage and support the patient to make a commitment to use no nonprescribed drugs by the end of treatment.
- Encourage the patient's participation in self-help groups.
- Provide skills training that is oriented to chronic and complex life problems, such as job-seeking.
- Provide aggressive diagnosis and treatment for comorbid psychiatric disorders, particularly depression and anxiety.

Provide comprehensive counseling that includes drug avoidance skills. Help patients to identify individual risk factors for specific drugs. Define and develop coping strategies - such as anger management and social skills development - for different situations that the patient is likely to encounter. Teach patients self-management and social skills that assist them to create steady and self-affirming social supports and drug-free contacts, resist coercion, and improve decisionmaking. Teach patients relaxation and meditation techniques to mitigate the effects of stress and tension that may lead to the use of drugs.

Maintaining Safer Sexual Practices

Safer sex requires a lifelong change in behavior. Maintaining these safer sexual practices and not returning to high-risk behaviors is a continuing challenge.

Factors that are associated with a return to high-risk sexual practices include higher levels of unsafe sexual activity prior to behavioral change, perceptions that behavioral change does not offer protection from infection, failure to use condoms with a steady and "safe" sexual partner, negative attitudes concerning condom use, use of alcohol and other drugs, a lack of enjoyment of the sexual activity using safer sex methods, a strong preference for high-risk sexual activities such as unprotected anal intercourse, and social support for high-risk behavior.

The following examples of counselor-based activities can support the patient in maintaining safer sexual practices.

- Counsel patients and their sexual partners regarding safer sexual practices, impediments to safer sex, and possible options for overcoming these impediments.
- Conduct educational and counseling sessions that incorporate different ethnic and cultural perspectives concerning the use of condoms.
- Offer coping skills and assertiveness training that assists patients in resisting pressures from partners to engage in unsafe sexual practices.
- Provide counseling and other support for patients who test positive for HIV disease. Patients may give up previous safer sex behaviors once positive test results are received. Discuss the patient's risk for

recurring infection, possible acceleration of disease, and the risk of infecting sexual partners if safer sexual practices are not maintained.

Provide case management services and followup support for patients, including referrals to medical care and social service agencies for housing, financial, educational, child care, employment, and legal assistance.

Endnote

¹. 21 CFR 291.505(d)(3)(i).

Sources

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Chapter 3 - Legal and Ethical Issues

Screening for infectious diseases among drug treatment populations offers an opportunity to identify infected individuals, provide timely medical care, and halt or slow the progression of disease. The screening process, however, may raise many difficult legal and ethical questions with respect to testing, reporting, and access to care. The implications of testing for human immunodeficiency virus (HIV), in particular, are complex. The privacy rights of patients, treatment needs, and protection of innocent parties are aspects of treatment that are not always comfortably integrated.

The following discussion is intended to provide direction for treatment providers concerning issues of access to treatment, confidentiality and informed consent, confidential and anonymous testing, testing of treatment staff, reporting of infectious diseases, contact tracing and partner notification, recordkeeping, the duty to warn, and environmental safety.

Access to Treatment

Research shows that drug treatment is effective and promotes the development of healthier, more productive members of society. Comprehensive treatment programs, which typically offer or provide referral for medical care, mental health services, social services, and infectious disease screening and treatment, are thought to be the most beneficial. These services should be available to all who need them. The Consensus Panel endorses the concept of comprehensive treatment.

Requiring individuals to be tested for infectious diseases as a condition of admission to treatment, refusing to admit otherwise eligible individuals, or providing differential treatment to such patients are practices that inhibit drug users from seeking treatment, and are actions that are likely to violate Federal and State nondiscrimination laws as well as being unethical. However, to protect the safety and health of the other patients and staff, an individual seeking treatment who is thought to have infectious tuberculosis or any other highly contagious disease such as chicken pox may be denied admission until it has been medically determined if the patient needs treatment prior to being admitted to the program.

Some accommodations by treatment providers may be needed to enable individuals to participate in and benefit from treatment services. Providers are required by Federal nondiscrimination laws to make reasonable accommodations for clients with disabilities, but not to change the basic nature of the services offered or incur undue financial hardship. For example, appointments for treatment services may need to be changed to accommodate a need of a patient with disabilities for more immediate medical care.

Segregating or providing differential treatment to persons with HIV or AIDS under the guise of protecting others from infection are practices that must generally be avoided. Other, nondiscriminatory means are usually available to protect patients and staff, and programs should implement them. Appropriate infection control and prevention measures include education and training for staff about transmission modes for HIV and other communicable diseases and preventive practices such as those detailed by the Centers for Disease Control and Prevention and the Occupational Safety and Health Administration ([CDC 1987, 1988](#); [OSHA 1991](#)). Treatment providers must be well trained in and up to date on these precautions and standards.

Confidentiality

The benefits of the therapeutic relationship that is so critical to the recovery of patients in treatment depend, in part, on maintaining strict confidentiality for all patient information and confidences. Patients in treatment rely on this standard of confidentiality when they enter care, and they continue to trust that their medical and personal records will be protected from unwarranted and unwanted disclosure.

The traditions of professional ethics and the desire to keep individuals from harm have protected patients' confidentiality and eventually led to legally protected rights of confidentiality. Federal laws and regulations now protect drug treatment patient records, and some State statutes may equal or exceed these Federal requirements.¹

In addition to the Federal confidentiality laws and regulations, treatment staff need to be familiar with the State confidentiality laws that affect the delivery of services in their particular communities. Similarly, patients in drug treatment programs must be told about the extent of the confidentiality protection provided by law, and when and if this protection does not exist. Discussion of the extent of confidentiality should be part of the initial interview with the patient.

Federal Laws and Regulations on Confidentiality of Drug Treatment Records

The following guidelines explain the Federal laws and regulations concerning the confidentiality of drug referral and treatment information.

General Prohibition of Disclosure

Federal confidentiality regulations prohibit disclosure of patient information as follows:

- Except under certain limited conditions, Federal confidentiality regulations prohibit the disclosure of records or other information concerning any patient in a Federally assisted drug treatment program.²
- The prohibition on unauthorized disclosure applies whether or not the person seeking information already has the information, has other means of obtaining it, enjoys official status, has obtained a subpoena or warrant, or is authorized by State law.³
- Federal law supersedes a State law that would permit or require a disclosure prohibited by the Federal confidentiality rules. However, States may have stricter regulations concerning confidentiality than the Federal regulations.⁴
- Redisclosure of patient-identifying information is prohibited unless such disclosure is made in compliance with Federal confidentiality regulations.⁵

Exceptions to the General Prohibition of Disclosure

Although the general rule is that patient-identifying information may not be disclosed, the regulations generally permit disclosures to be made with patient consent, and set out a number of circumstances in which disclosures may be made without patient consent. Each of these conditions or circumstances has its own requirements and limitations. In general, permitted disclosures are those made as follows:

- With the written informed consent of the patient
- Pursuant to internal program communications
- Pursuant to a medical emergency
- In response to a special court order following a court hearing in which disclosure is authorized
- For the purpose of reporting a crime at the treatment program or against program personnel
- For research or audit purposes
- In the course of reporting child abuse or neglect
- Pursuant to a qualified service organization agreement⁶
- In response to a request for non-patient-identifying information

State Laws on Confidentiality of Drug Treatment Records or Other Medical Information

A variety of State confidentiality laws may affect how services are provided to patients. These laws may control the release of medical records; limit the ability of persons to testify in court based on information obtained when providing professional services (testimonial privilege); or prohibit disclosure of information regarding specific diseases, such as HIV and drug use. Service providers and drug treatment staff should consult with local counsel to determine which State confidentiality laws affect their practices and develop protocols and training programs to help ensure that these laws are followed. Confidentiality is integral to the drug treatment process. Without confidentiality regulations, the patient may be discouraged from even seeking treatment, fearing the invasion of privacy and the exposure of sensitive, personal information.

Infectious Diseases Testing

There is no doubt that testing for infectious diseases can benefit patients in treatment as well as the community at large. Testing for HIV, hepatitis B, tuberculosis, and syphilis and other sexually transmitted diseases is strongly advocated for treatment populations, as it can lead patients to seek appropriate medical care, initiate preventive actions, and interrupt the transmission of disease to others.

Patients generally have the right to be informed of the meaning and implications of a positive test for infectious disease, especially HIV infection. For example, there is currently no cure for AIDS, and a positive HIV test result may be extremely distressing to some patients, even threatening their recovery effort. There is, however, clearly a benefit from treatment of HIV infection.

Historically, there has been some concern in drug treatment programs that the risk involved by testing for HIV - a potential for return to drug use - outweighed any gains, particularly if it was anticipated that the result was going to be positive. Therefore, some drug treatment centers discouraged early testing, believing that the risk of return to drug use far outweighed the benefits of knowing HIV status. This position evolved at a time when very little could be done in the way of prophylactic treatment and maintenance and promotion of health of the HIV-positive individual. Currently, there are a number of effective treatments - prophylactic and otherwise - for people who are HIV positive, and the benefits of knowing HIV status and initiating early treatment far outweigh the risk of return to drug use. Drug treatment providers are encouraged to recommend to their patients that they be tested and identify their status.

Despite the benefits or because of the risk of emotional distress, or for other reasons, some patients may choose not to undergo testing. Treatment providers need to be respectful of these choices. Patients generally have the right to refuse to be tested for infectious diseases and cannot be denied access to or continuation of treatment services based solely on that refusal.

For patients who agree to testing, the Consensus Panel recommends that consent should be obtained before any testing begins. Informed consent is required for HIV testing in many jurisdictions. In some States, minors can give informed consent without parental agreement.

State laws generally govern whether and what form of informed consent is required for medical testing (including infectious disease testing). Drug treatment providers should make sure their consent forms for HIV or other infectious diseases testing comply with applicable State laws.

Informed consent consists of communicating to the patient the risks involved and benefits to be derived from a test in a way that allows the patient to make a decision about whether or not he or she will have the test done. The practitioner involved in securing the patient's informed consent will generally include a note in the patient's record. Written informed consent requires the patient's signature on a document that specifies the above elements in a language that the patient is comfortable with. If written informed consent is required in a particular institution or jurisdiction, the consent should conform with the established guidelines of the institution or jurisdiction. If there is any question about the process, legal counsel should be sought.

Issues Concerning HIV Testing

The circumstances under which testing for HIV infection should occur have been the subject of continuing debate for a decade, although in some States, laws have resolved the issue. Arguments for mandatory versus voluntary and confidential versus anonymous testing are yet to be settled elsewhere. Anonymous testing assigns a unique identifier to each patient, and results are not traceable to an individual. Confidential testing, on the other hand, links the individual by name to test results, and confidentiality safeguards protect the test results.

The Centers for Disease Control and Prevention, the Consensus Panel, and many other professional health care associations represent the public health consensus, which strongly urges voluntary and confidential or anonymous testing for individuals at high risk for HIV.

Under current Federal law, mandatory HIV testing is required on entrance to the military; for donors of blood, organs, and tissue; Federal prisoners; and persons seeking immigration to the United States (Screening for HIV 1989). States may also require mandatory testing of individuals under certain circumstances, such as marriage applicants, mentally ill or mentally retarded patients, injection drug users, and sex offenders ([Gostin 1989](#)). In some States, the law requires the reporting of infected individuals to health authorities.

The unfortunate discrimination that persists for many HIV-positive individuals makes it particularly imperative that treatment providers act with great care to inform patients of their legal rights concerning testing. Patients need to receive professional counseling before reaching a decision about HIV testing; in some States, HIV laws mandate pre- and post-test counseling. This counseling should provide patients with important information that may affect their decisionmaking process concerning the transmission of HIV, informed consent, testing procedures, possible results, reporting requirements, and available treatments.

For patients who agree to seek HIV-antibody testing, confidential as well as anonymous procedures are available in many communities and should be discussed as alternatives with patients. In States that require the reporting of HIV-positive individuals by name to health authorities, patients may choose to use anonymous testing sites.

Reporting of Infectious Diseases

Certain infectious diseases are reportable to health authorities under State statutes and regulations. There are many variations among States concerning conditions and diseases to be reported, timeframes for reporting, agencies that should receive reports, persons required to report, conditions under which reports are required, and penalties for not reporting. In most States, local health departments rather than State health departments are the recipients of infectious disease reports. The patient needs to be made aware of these State regulations

while at the same time being reassured that this information is confidential and will not be released inappropriately.

Treatment providers should seek information about the requirements of their State and develop protocols and training programs to ensure compliance. Trained health department personnel are able to provide contact tracing and notifications. A summary of general aspects of reporting follows.

Tuberculosis

All cases of active, infectious tuberculosis must be reported immediately to health authorities ([CDC 1989](#)). Confidential patient information is usually protected under State law.

Hepatitis

All cases of potentially communicable viral hepatitis must be reported immediately to health authorities ([APHA 1990](#)). Confidential patient information is usually protected under State law.

Syphilis

All cases must be reported immediately to health authorities ([CDC 1990](#)). Confidential patient information is usually protected under State law.

Other Sexually Transmitted Diseases

Reporting requirements vary significantly by disease and jurisdiction. For example, case reporting of gonorrhea is required by all States, chancroid is reportable in many States, and herpes simplex and chlamydia are reportable in only some States ([Benenson 1990](#)). Confidential patient information is usually protected under State law.

HIV and AIDS

All States require the reporting of AIDS cases, as defined by the Centers for Disease Control and Prevention, to health departments. A growing number of States specifically or implicitly require reporting of HIV-positive test results. Some, but not all, of these States require that names of individuals with positive test results be reported. The confidentiality of all reportable information is usually safeguarded by State law. Partner notifications may be conducted by trained health department personnel or health care providers at the request of patients, or by patients themselves.

Contact Tracing and Partner Notification

Many contacts and partners of infected persons are unaware of their risk for disease. The tracing and notification of these individuals gives them the opportunity to receive testing and necessary therapeutic treatment. Preventive risk reduction education and counseling can be provided when appropriate. Furthermore, surveillance data on infection rates, geographic clustering, and other information are available for the development and implementation of successful public policies for disease prevention and infection control.

Public health statutes in States usually authorize or require contact tracing for sexually transmitted diseases. Most States currently do not classify HIV infection as a sexually transmitted disease, although some States have specifically authorized or required such tracing. The informed consent of the patient must be sought for contact tracing and partner notifications in circumstances where statutes are silent. All notifications that are accomplished by persons other than the patient, regardless of the reporting requirement, are performed without revealing the identity of the patient.

While the name of the infected person is not revealed, it may be inferred by the partner in some situations. These notifications may place patients in treatment at risk for negative consequences, such as physical abuse or abandonment. Treatment providers should exercise care to protect patient confidentiality when counseling about, assisting with, or performing partner notifications and contact tracing.

Public health statutes in all States require notification to the Public Health Service of all cases of known or suspected active tuberculosis. In addition, the health department will notify any persons they believe may have been exposed to active tuberculosis. Laws mandate appropriate followup and treatment of anyone who may have acquired tuberculosis from a known exposure to an active case of tuberculosis.

Treatment Program Recordkeeping

Treatment programs have a duty to maintain records about patients in treatment to ensure adequate care. Data from treatment records are useful in monitoring patient progress, case management, seeking funding and reimbursement, and evaluating program effectiveness. Infectious disease test results may be part of the patient's treatment record. Access to records that contain this information must be kept strictly confidential, and the file that contains the information should be locked. Access to the file should be restricted to specified individuals. In States in which there are laws covering disclosure of HIV in health records, drug treatment programs need to comply with restrictions about mentioning HIV diagnosis and treatment in any patient's drug treatment records.

A number of approaches for patient recordkeeping are possible. Treatment providers should ensure that the approach selected meets all Federal- and State-prescribed requirements for confidentiality and management of HIV information where specified. Options may include

- Maintaining a single, comprehensive record with test results integrated throughout the record and limiting access to medical staff and others authorized to have access to medical information by consent of the patient.
- Maintaining infectious disease and/or HIV test results separately from the main part of the patient's record and limiting access to medical staff and others authorized to have access to medical information.
- Maintaining all medical information separately from the main part of the patient's record and limiting access to medical personnel and others authorized to have access to medical information ([Legal Action Center 1991](#)).

Disclosures of Infectious Disease Information

Treatment providers need to be prepared to inform patients about any disclosure of confidential information made with their consent. Treatment providers also should have procedures in place concerning the notification of patients when information is permitted to be and is released without their consent. There are times when it may not be in the patient's best interest to sign a consent or when the patient may simply not want to sign a consent. Treatment programs can help the patient determine if signing a consent is in his or her best interest.

The Duty to Warn

In spite of strict ethical codes and legal requirements for the confidentiality of patient information, some treatment providers may find themselves under a "duty to warn" that may require a breach of confidentiality. "Duty to warn" refers to the legal duty of a physician, health care worker, or other professional to protect another individual from harm. Treatment providers may be faced with and should be prepared to resolve the conflicting obligations to protect the patient's right to confidentiality, and the duty to warn a third party. The duty to warn issue is, however, a legal issue that should be addressed through legal channels when necessary.

The legal basis for warning an individual in order to protect that person from severe or deadly harm may be provided by State law. If so, it is most likely that the State statutes allow, but do not require, that a warning be

made. The moral duty to warn conflicts with the legal and professional sanctions against unauthorized disclosure of confidential patient information.

Drug treatment providers must keep in mind that, even if State law permits or requires disclosures of patient-identifying information in "duty to warn" situations, they may make such warnings only in ways that are permitted by the Federal drug confidentiality laws and regulations.

Treatment providers should be aware of applicable State laws, have procedures in place that support legally required actions, and understand that a breach of confidentiality is punishable by law.

Endnotes

¹. 42 USC 290dd-3 and 290ee-3; 42 CFR, Part 2.

². 42 CFR 2.12-2.13(a).

³. 42 CFR 2.13(b)-2.20.

⁴. 42 CFR 2.20.

⁵. 42 CFR 2.32.

⁶. A *qualified service organization agreement* allows a drug treatment program to communicate patient-identifying information to another organization that provides the treatment program with a necessary service without a specific consent for each communication. The agreement binds the other party to respect all confidentiality requirements. 42 CFR 2.11 and 2.12 (c)(4).

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Chapter 4 - Issues for Treatment Program Administrators: Staff and Community Development and Environmental Safety

Drug use places individuals at risk for infectious diseases. As a result, treatment providers are increasingly aware that patients may need medical care, psychosocial services, and other resources, in addition to drug treatment. Treatment staff must be knowledgeable about infectious disease risk factors, screening procedures, and the impact such diseases may have on the course of drug treatment. In addition, treatment providers must be prepared to access a range of community-based services on behalf of their patients.

The following section addresses staff and community development issues for consideration by treatment program administrators. These issues include

- Training staff to identify patients who are at risk for infectious diseases
- Testing and vaccinating staff for certain infectious diseases
- Assisting staff to overcome denial and resistance that may inhibit infectious disease screening and prevention efforts
- Developing support networks for staff
- Participating in community-based infectious disease screening and prevention efforts

- Environmental safety

Staff Awareness and Training

Drug treatment staff are in an advantageous position to ensure that infectious disease screening is available to their patients. Many staff, however, may have little knowledge of or training in infectious disease screening.

Treatment staff need to be knowledgeable about infectious diseases that are common in treatment populations. It is essential to provide training on the risk factors for infection, risk reduction and retention in treatment strategies, symptoms of disease, screening procedures, and the range of appropriate medical treatments. Staff must also receive any assistance that may be needed to explore and resolve uncomfortable feelings and negative attitudes concerning the sexual practices and risk-taking behaviors of patients that may lead to infection.

Infectious diseases, particularly life-threatening ones such as AIDS and multidrug-resistant tuberculosis, can evoke strong reactions in staff. For example, some staff may feel uncomfortable and poorly equipped to interact with patients who are HIV positive. Feelings of anger toward women whose infants have been infected with sexually transmitted diseases and HIV may surface. The strong denial and depression of some infected patients may frustrate and discourage staff members who reach out to them. Self-doubt about their effectiveness can affect even well-trained and experienced treatment professionals.

Exploring Feelings and Attitudes About Sexual Practices

Many of the infectious diseases addressed by this TIP are transmitted through sexual practices. Straightforward discussions with patients of their sexual practices can be important to their recovery and reduce the risk of infection.

Staff may encounter sexual orientations, behaviors, attitudes, and language quite different from their own. Behavioral standards held by staff may vary considerably from those held by some patients, and may be influenced by strongly held religious beliefs, cultural values, and other factors. Staff must be comfortable with their own sexuality and be willing to accept, without judgment, the differences of others.

Group discussions, informal seminars, and individual counseling can encourage staff to bring to the surface, acknowledge, and examine their own feelings and attitudes about sexual behaviors. Treatment programs that offer supportive training for staff can help them to develop accepting and nonjudgmental attitudes and create a climate of understanding in which patients can explore and change their behaviors.

Treating Patients Who Are HIV Positive

It is one thing to theorize about the issues raised by HIV infection, but another to confront them when treating people living with HIV and AIDS. The HIV epidemic has led to increased psychological demands on drug treatment staff: patients do not get permanently well; the disease process is uncertain; and personal fears of infection may surface.

Some staff may find themselves angry and resentful about having to work with patients who are ill and even dying. Other staff may be able to support individuals in their recovery from drug use, but may not be prepared to work with patients who never get well.

Treatment programs with HIV-positive patients can take a variety of actions to support staff and patients:

- Develop a program to continually inform staff and discuss with them the rapidly changing scientific information about HIV infection, including disease manifestations, opportunistic infections, and available treatments. Display brochures and toll-free telephone numbers for the Centers for Disease Control and Prevention (CDC) National AIDS Clearinghouse, and the AIDS Clinical Trials Information

Service (ACTIS) so that staff can easily obtain information.¹ Place the program on mailing lists to receive updated materials on HIV and AIDS.

- Train staff regarding the CDC's universal blood and body fluid precautions to prevent exposure to HIV, hepatitis B, and other bloodborne pathogens^{2,3}, and the Occupational Safety and Health Administration (OSHA) standards.⁴
- Provide structured opportunities in a supportive atmosphere for individual staff to discuss their feelings regarding the demands and pressures that are placed on them.
- Develop and maintain an updated resource file of community services.
- Establish referral relationships with caregivers who specialize in HIV and AIDS.

Facing Personal Risk Factors

Many staff of treatment programs are recovering from drug use and may view themselves as being at increased risk for infectious diseases. Some staff may be unable to face their own concerns about infection. As a result, they may resist discussing HIV and AIDS with patients, or avoid patients who test positive for this and other diseases. Staff who previously viewed themselves as competent may now consider themselves incompetent to work with some patients, particularly those who are HIV positive.

Treatment program administrators must be prepared to help staff acknowledge and gain insight into their feelings about possible infection with HIV and other infectious diseases. Strong resistance to and denial of these feelings can destroy the therapeutic relationship. These staff members will be less able to cope with the transference of patient feelings or may react to a patient with inappropriate emotional responses. Such unresolved feelings can also undermine staff retention.

Administrators need to understand that individual staff may not be able to work with every patient. Some staff may need additional training; others may require reassignment.

Testing and Vaccinating Program Staff

Treatment program staff who are in contact with patients are at increased risk for infection. The CDC recommends that treatment programs regularly test both staff and patients for tuberculosis and provide for appropriate medical care (CDC n.d.). The Consensus Panel is in accordance with the Occupational Safety and Health Administration Guidelines (OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030), which states that all employees whose jobs involve the risk of directly contacting blood or other potentially infectious materials (OSHA Categories I and II) must be offered hepatitis B vaccine free of charge. An employee who refuses to receive the hepatitis B vaccine must sign a vaccination declination form.

Coping With Resistance to Risk Reduction

Risk-reduction strategies require patients to change their behavior to prevent disease and to promote a healthier lifestyle. Two highly successful strategies to reduce the risk of infectious diseases are abstinence from drugs and use of safer sexual practices. Research indicates, however, that some patients may not implement these risk-reduction behaviors and, if they are implemented, may relapse often.

Staff may find it frustrating to treat patients who do not follow their suggestions about risk-reduction behaviors and, as a result, jeopardize their own and others' health. Treatment programs can address these frustrations by creating an open and supportive environment, establishing internal staff support groups, and identifying professional support groups in the community that can be resources for staff.

Valuing Cultural and Religious Values, Beliefs, and Traditions

Throughout treatment, patients respond to staff and the treatment process from the perspective of their cultural and religious values, beliefs, and traditions. For example, the meaning and significance of certain sexual

practices and expressions may differ sharply in various cultures. Religious teachings about relationships, contraception, and other issues can be diverse.

The cultural and religious backgrounds of patients provide the context in which recovery from addiction and infectious disease risk-reduction efforts take place. It is especially critical that staff are aware of the nature and implications of the cultural and religious values, beliefs, and traditions of patients.

Developing Staff Support Networks

The high demand for drug treatment can place extraordinary demands on program personnel. The chronic nature of drug dependence, a lack of resources in the community, and other factors may lead to staff burnout and turnover. The emotional demands of treating the growing number of patients who are living with HIV and AIDS may contribute to staff demands.

To assist staff in their treatment efforts, treatment programs can provide for and support professional networking activities. They can

- Establish informal support groups within the program that provide staff with opportunities to share their individual experiences and problems.
- Provide information about existing community-based and professional groups and associations that offer opportunities for professional training and education.
- Inform staff about referral resources for individual counseling, volunteer experiences, and other personal development activities.

Environmental Safety

Treatment providers need to provide for the safety of patients and staff by having in place policies and procedures that minimize the risk of infectious disease transmission, whether the setting is outpatient, residential, or hospital based.

The magnitude of the risk of disease transmission for staff varies considerably by type of treatment setting, patient population served, job duties, and area of the facility in which a person works. For example, the risk of tuberculosis infection may be higher in areas where patients are congregated, such as waiting rooms, prior to any examination.

The risk to patients of infection from treatment staff exists as well. Hepatitis B may be spread to a patient by an infected health care worker during certain invasive procedures where the health care worker may sustain a needlestick or laceration, resulting in possible exposure of the patient to infected blood. Although transmission of HIV from infected workers to patients has been extremely rare, transmission during invasive procedures remains a possibility. The use of universal precautions during the drawing of blood or other invasive procedures should be implemented.

The screening of patients in treatment for infectious diseases reduces the risk of disease transmission to other patients. The early identification, placement in respiratory isolation, and treatment of persons with active tuberculosis, in particular, should be an important consideration for treatment providers. For patients with acute viral hepatitis, guidelines on the precautions for handling blood and body fluids must be followed. For a patient with suspected or confirmed secondary syphilitic dermatitis, contact isolation is appropriate and, therefore, gloves should be worn by the caregiver.

Environmental Precautions To Prevent the Spread of Tuberculosis

In addition to testing and medical treatment, other precautions may be needed to prevent or reduce the spread of tuberculosis and, more recently, multidrug-resistant tuberculosis, among treatment populations and staff. These methods include

- Local exhaust ventilation to the outside that removes airborne contaminants at or near their sources.
- General ventilation that provides for dilution, air mixing, and negative air flow in rooms where a patient with possible tuberculosis may be coughing or sneezing as well as in rooms where sputum is induced or aerosolized pentamidine is administered.
- Use of HEPA filters if air is recirculated.
- Installation of ultraviolet (UV) lamps in exhaust air ducts as well as in patient care areas. In patient care areas, the UV light source must be shielded to prevent possible exposure of patients or employees to UV light.
- Cleaning, disinfecting, and sterilizing patient-care equipment ([CDC 1990](#)).

State or local health departments can help drug treatment centers set up programs to protect their patients and themselves. The Centers for Disease Control and Prevention also publishes relevant guidelines and educational materials, including *What Drug Treatment Centers Can Do To Prevent Tuberculosis*. This document provides information about tuberculosis infection, screening, and preventive therapy, and provides recommendations for prevention of the spread of tuberculosis in drug treatment centers.

Other Published Guidelines and Advisories for Infectious Disease Prevention and Control

Drug treatment providers can play an important part in the screening and treatment of patients and staff for infectious diseases. Treatment populations are at high risk for certain infections, and their recovery and well-being can be improved by the careful application of screening policies, provision of appropriate care, and the implementation of environmental and procedural safeguards.

A variety of guidelines and advisories have been prepared to assist health care professionals and treatment providers in the prevention, screening, and treatment of infectious diseases. The following guidelines and advisories provide information and direction for treatment programs:

- Centers for Disease Control. *Recommendations for Prevention of HIV Transmission in Health-Care Settings*, August 1987 - presents the universal blood and body fluid precautions to be used for all patients regardless of their bloodborne infection status. Precautions are pertinent for HIV, hepatitis B, and other bloodborne pathogens.
- Centers for Disease Control. *Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens In Health-Care Settings*, June 1988 - clarifies and supplements the preceding report as it relates to particular body fluids, use of protective barriers, use of gloves for phlebotomy, selection of gloves, and changes in waste management programs.
- Title 29 Code of Federal Regulations, Part 1910.1030. Occupational Exposure to Bloodborne Pathogens 1991 - presents the Occupational Safety and Health Administration's bloodborne pathogens standard and informs employees and employers of the risks of occupational exposure to such pathogens and how to reduce these risks.
- Centers for Disease Control. *Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS*, August 1987 - presents recommendations for HIV testing, pre- and post-test HIV counseling, and the confidentiality of personal information.
- Centers for Disease Control. *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings, with Special Focus on HIV-Related Issues. Morbidity and Mortality Weekly Report*. Vol. 39, No. RR-17, December 7, 1990 - makes recommendations for reducing the risk of transmission to persons in health-care settings - including workers, patients, volunteers, and visitors.
- Centers for Disease Control. *Prevention and Control of Tuberculosis in U.S. Communities With At-Risk Minority Populations. Morbidity and Mortality Weekly Report*. Vol. 1, No. RR-5, April 17, 1992 - recommendations of the Advisory Council for the Elimination of Tuberculosis for programs and services that will contribute to the elimination of tuberculosis in communities with at-risk racial/ethnic minorities.
- Centers for Disease Control. *National Action Plan to Combat Multidrug-Resistant Tuberculosis; Meeting the Challenge of Multidrug-Resistant Tuberculosis: Summary of a Conference; Management*

of Persons Exposed to Multidrug-Resistant Tuberculosis. *Morbidity and Mortality Weekly Report*. Vol. 41, No. RR-11, June 19, 1992 - presents three reports on MDR-TB: National Action Plan to Combat MDR-TB; summary of a CDC-sponsored national conference on MDR-TB; and practical guidelines for clinicians who manage persons exposed to patients infected with MDR-TB.

- Centers for Disease Control. *Update on Adult Immunization - Recommendations of the Immunization Practices Advisory Committee (ACIP)*. *Morbidity and Mortality Weekly Report*. Vol. 40, No. RR-12, November 15, 1991 - provides information on vaccine-preventable diseases; indications for use of vaccines, toxoids, and immune globulins recommended for adults; and specific side effects, adverse reactions, precautions, and contraindications. Provides immunization recommendations for adults in specific age groups and for adults with special immunization requirements because of occupation, lifestyle, travel, environmental situations, and health status.
- Title 42 Code of Federal Regulations, Part 2. Federal Regulations on Confidentiality of Alcohol and Other Drug Treatment Records - presents regulations concerning the disclosure of patient information, including the limited conditions under which disclosures are permitted.
- Centers for Disease Control. Recommendations for Prophylaxis Against *Pneumocystis carinii* Pneumonia for Adults and Adolescent Infection With Human Immunodeficiency Virus, by U.S. Public Health Service Task Force on Antipneumocystis Prophylaxis for Patients With Human Immunodeficiency Virus Infection. *Morbidity and Mortality Weekly Report*. Vol. 40, No. RR-12, 1992 - prophylactic agents and regimens for adults and adolescents are recommended and discussed.
- Centers for Disease Control. Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures. *Morbidity and Mortality Weekly Report*. Vol. 40, No. RR-8, July 12, 1991 - presents recommendations to provide guidance for prevention of human immunodeficiency virus and hepatitis B virus transmission during exposure-prone invasive procedures.

Community Development

The use of drugs and incidence of infectious diseases are not restricted to certain population groups or geographic areas. They are problems that exist in all communities, and group efforts are needed to prevent and treat them.

Drug treatment programs must be part of the fabric of community life. The recovery of their patients depends, in part, on how well they contribute to and are linked with the resources of the community. The following initiatives can strengthen community and treatment program resources and responsiveness to patient needs:

- Initiating and participating in education and training efforts to inform community residents and other service delivery staff about drug use and infectious diseases, including incidence and prevalence data, transmission routes, high-risk behaviors, symptoms, and treatments. Education and training sessions can be offered in schools and for church groups, civic organizations, and professional associations.
- Seeking information and training support from community-based organizations and targeting audience groups. Community members can be invited to share and discuss with staff their traditions, cultural values, and religious perspectives.
- Facilitating and participating in networking among health care agencies, social service organizations, mental health providers, patient support groups, and representatives of populations at risk for use of drugs and infectious diseases.
- Assigning staff to represent the treatment program as part of interagency efforts to develop and enhance the service delivery system. Opportunities can be identified to foster greater understanding, develop new initiatives, consolidate resources, identify and fill gaps in service, and create referral agreements.

Endnotes

¹. Centers for Disease Control and Prevention National AIDS Clearinghouse, P.O. Box 6003, Rockville, MD 20850. 1-800-458-5231. AIDS Clinical Trials Information, P.O. Box 6421, Rockville, MD 20850. 1-800-874-2572. See also [Appendix D - Resource](#)

List.

². Centers for Disease Control. Recommendations for prevention of HIV transmission in health-care settings. *Morbidity and Mortality Weekly Report* 36 (Supplement No. 2):1987.

³. Centers for Disease Control. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *Morbidity and Mortality Weekly Report* 37(24):377'388, June 24, 1988.

⁴. 29 CFR, Part 1910.1030.

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Chapter 5 - The Initial Patient Contact

Individuals may enter drug treatment programs by a variety of pathways. Referrals from the courts, physicians, and social service agencies are common, as are self-referrals. Regardless of how the patient enters care, the initial patient contact establishes the basis for ongoing drug treatment, infectious disease screening, medical care, and the continuum of supportive services that are vital to the patient's recovery and health.

Introduction

The goals of the initial patient contact are to

- Initiate a positive relationship between treatment staff and the patient
- Obtain a thorough and complete medical, sexual, psychosocial, and drug use history
- Prepare for the initial physical examination and infectious disease screening
- Begin treatment planning

The Key Role of the Interviewer

Studies show that an open, trusting relationship with treatment staff helps the patient to remain in and benefit from treatment services. The interviewer can begin creating this supportive relationship with the patient during the crucial first contact.

Characteristics of the interviewer that help establish such a relationship are an accepting and nonjudgmental attitude, a willingness to provide complete information about assessment and diagnostic procedures, a willingness to answer the patient's questions, and an ability to be open to and understanding of the needs and concerns of the patient.

A comfortable rapport encourages the patient to trust the interviewer with sensitive and personal information. To further facilitate patient responsiveness, the interviewer can

- Introduce the objectives of the interview and explain to the patient that the questions asked are intended to help both treatment staff and the patient plan for and provide appropriate care.
- Explain to the patient how Federal, State, and local laws and regulations affect the confidentiality of drug treatment information, infectious disease test results, contact tracing and partner notification procedures, and medical records.
- Inform the patient that testing for infectious diseases, including human immunodeficiency virus (HIV), is voluntary.
- Begin the process of taking a history with the least stressful areas of questioning. For example, gather general demographic information first, then address drug use, sexual practices, and infectious disease testing later in the interview.

Gathering a Patient History

A variety of protocols are used by drug treatment programs to obtain a patient history and to guide treatment planning. These protocols may include the use of standardized or program-modified questionnaires. Questionnaires may be partly self-administered by patients or treatment staff may complete them using an interview process.

Questionnaires and the interview process should obtain a clear picture of patient risk factors for infectious disease. Key areas and their significance for infectious disease screening and treatment planning follow.

Medical History

History of and Treatment for Infectious Diseases

The patient who has a history of certain infectious diseases, such as those that are sexually transmitted, is at increased risk for possible reinfection and co-infection. For example, the patient with one sexually transmitted disease (STD) is at increased risk for other STDs; the patient who is HIV positive is at increased risk for co-infection with tuberculosis.

The patient's history of treatment for infectious diseases may provide important clues for interpreting subsequent test results. The history of an allergic or adverse reaction to any nonprescription or prescription drugs used in the past, and any contraindicated medications, as well as other health problems, should be obtained and noted in a prominent place in the clinic chart.

Vaccination Status

A vaccine is available for hepatitis B. The patient with no serologic evidence of prior exposure should be offered hepatitis B vaccine to prevent future infection. Persons at risk for HIV may benefit from vaccination for other diseases for which vaccines are available.

Current Medical Treatments

Drug treatment staff must coordinate patient care with other health professionals who may be providing medical treatment for infectious diseases and other health conditions. Followup by drug treatment staff can ensure that the patient continues to receive needed medical care.

Obstetrical/Gynecological Status

The early detection of infectious disease among pregnant drug-using women will help ensure that appropriate medical care for the mother and fetus is provided, contraindicated medications are avoided, and family planning counseling is offered.

History of Drug Abuse

History of Injection Drug Use

Injection drug use is strongly associated with the risk of infection in drug users. The most important variable determining whether or not a person will be infected with any given disease is the infectivity rate in that person's cohort. In the instance of injection drug use, the cohort will consist of the people with whom the user has shared needles and syringes and other contaminated paraphernalia as well as the sex partners of the user. HIV, hepatitis B, and syphilis can all be transmitted through contaminated equipment. These diseases can be transmitted to sex partners through unsafe sex practices.

History of Sharing Needles and Other Drug Paraphernalia

The sharing of needles, syringes, drug vials, and cookers can transmit infection since any part of this equipment may be contaminated. The more persons with whom the patient has shared needles and other contaminated equipment, the higher the risk of infection.

Attempts to sterilize needles or to use new needles should be carefully discussed. "New" needles and syringes sold to injection drug users by street sources may actually be recycled ones. Patients must be urged to not share drug paraphernalia and told that cleaning syringes, needles, or other drug paraphernalia with bleach may not kill the HIV virus. Treatment centers should contact the Centers for Disease Control and Prevention frequently to obtain updated guidelines on the disinfection of drug injection equipment. See [Appendix G](#) for new information on the limitations of bleach and proposed recommendations to prevent HIV transmission via shared injection equipment.

Psychosocial History

Family History of Infectious Disease

Patients may be at increased risk for certain infectious diseases based on their family history. Tuberculosis and hepatitis B, for example, can be transmitted through contact with infected family members.

Psychiatric Disorders

If psychopathology is present and not treated aggressively, it may impair a patient's ability to engage and be retained in treatment. The counselor should inquire about psychological or psychiatric problems that may be present in some people who use drugs.

Socioeconomic and Housing Status

Lower income, homelessness, and residence in crowded and poorly ventilated living conditions (such as prisons, migrant worker camps, and residential mental health facilities) are associated with an increased risk of developing tuberculosis. Hepatitis B is associated with drug use, lower socioeconomic status, and residence in a long-term facility. A lack of income may also result in the patient engaging in unsafe sexual practices in exchange for money, drugs, or shelter.

Sexual History

The sexual history provides a basis on which to assess the patient's risk for certain infectious diseases, to plan for appropriate medical care, and to develop risk reduction and relapse prevention strategies. Initial questions concerning intimate sexual practices and episodes should be of a general nature. The interviewer can proceed gradually to more specific practices and events as is appropriate to and comfortable for the individual patient.

Some patients, for example, may indicate they have a stable, long-term relationship and do not engage in high-risk behaviors such as the exchange of sex for drugs, money, or shelter. As a result, questions about multiple sexual partners can be brief. Other patients may provide information that suggests multiple, high-risk sexual contacts and practices. In these cases, information about specific sexual practices and the circumstances of the sexual encounters may be appropriate.

It may be helpful during this process to assure the patient that a sexual history provides the treatment team with information that can be critical for the prevention and treatment of infectious diseases, and that this is the only purpose for gathering such information. The interviewer should briefly discuss the link between infectious diseases and drug use, and identify and probe, as appropriate, the following areas of sexual practice that are risk factors for infectious diseases.

Number and Background of Sexual Partners

Having, or having had, more than one sex partner increases a person's risk factor for contracting sexually transmitted diseases, HIV infection, and hepatitis B. The greater the number of past sex partners, the greater the risk. The risk of infection also increases if a person's partners have or have had multiple partners and if unsafe sex practices occur.

The geographic location of the patient's sexual encounters is significant since some areas in the United States have a higher incidence of certain infectious diseases. In addition, the risk of infection increases when sexual encounters have occurred in settings such as prisons, due to an increased likelihood of unprotected and multiple sexual encounters.

High-Risk Sexual Practices

There are some sexual practices more likely than others to place the patient at risk for infection, such as anal intercourse and group sex. Information about preventive practices is relevant, including the use of condoms and spermicidal products containing nonoxynol-9.

Sexual Activity While Under the Influence of Alcohol or Other Drugs

People are more likely to engage in unintended and unsafe sexual practices while under the influence of alcohol or other drugs because of the disinhibitory effect of these substances.

Sexual Abuse History

Many of the women - and men - seeking treatment are the victims of physical abuse, sexual abuse, or both. As a result, patients of all ages are at risk for sexually transmitted diseases and HIV. Repeated infections of STDs due to abuse and victimization are not uncommon.

Conducting a Medical Examination

Every patient entering alcohol and other drug treatment should have a thorough physical examination. This examination should

- Assist medical staff to diagnose infectious diseases in patients
- Provide a basis for infectious disease testing
- Assist medical staff to plan for and provide medical care for patients with infectious diseases
- Provide a basis for planning preventive interventions
- Provide a basis for planning followup medical care

The clinical symptoms, screening protocols, and treatments for tuberculosis, hepatitis, HIV and AIDS, and syphilis and other sexually transmitted diseases are discussed in detail in other sections of this TIP.

Preparing a Treatment Plan

A comprehensive drug treatment plan for the patient is based, in part, on information that is gathered through the initial interview process and during the physical examination. The treatment plan, which should be discussed with and developed in concert with the patient, must include screening and medical care for infectious diseases. Changes to this plan may occur throughout the course of treatment as is appropriate to the patient's progress toward treatment goals. The following considerations for infectious disease screening are relevant to drug treatment planning.

Screening and Vaccination

- All patients in treatment are at increased risk for infectious diseases and should be screened for HIV, hepatitis B and C, tuberculosis, syphilis, and for other sexually transmitted diseases if appropriate.
- If possible, HIV status should be determined at the time of entry. HIV testing should be done only with the consent of the patient. Pre- and post-test counseling must be available.
- Methadone clinic patients must be tested for syphilis and tuberculosis as required by Federal regulations.¹
- Followup testing should be scheduled at appropriate intervals for patients treated for infectious diseases.
- Patients found to not have serologic evidence of prior hepatitis B infection and who have not received hepatitis B vaccine should be given the hepatitis B vaccine.

Continuum of Care Services

- Medical treatment and followup of patients who test positive for infectious diseases should be provided.
- Advocacy services should be provided for patients with HIV and AIDS.
- Psychological, life management, legal, child care, and social support services should be provided as needed.

Risk Reduction and Retention in Treatment

- Risk reduction interventions, including education and counseling about safer sex practices and birth control should be offered to both men and women. Often women may be told that condoms are effective for disease prevention and birth control; however, they should be warned that condoms can break, and for maximum birth control protection, oral or barrier methods should be used in conjunction with condoms. The use of a spermicide can also give some additional protection against bacterially transmitted STDs.
- Interventions appropriate to retaining the patient in treatment should be identified. If called for, a followup appointment should be scheduled.

Endnote

1. 21 CFR 291.505(d)(3)(i).

Chapter 6 - Summary Statement on Tuberculosis

Tuberculosis (TB) is a major public health problem both in the United States and worldwide. After 30 years of a declining incidence of new cases, in 1985 the number of new cases of TB began to increase in the United States; from 1985 to 1991, there was an 18 percent increase in the number of new cases. The greatest increases have occurred among young adult African Americans and Hispanics living in large cities. Increases have been noted among persons who are infected with the human immunodeficiency virus (HIV), many of whom are injection drug users. The increase in new cases is occurring primarily in areas with high rates of HIV/AIDS, i.e., urban areas with a large, poor, minority population. The rise in new cases of TB is closely linked to the HIV epidemic. In addition, an increase in outbreaks of TB in a variety of settings (correctional facilities, homeless shelters, nursing homes, hospitals, drug treatment centers) is also contributing to the increase of TB.

Major outbreaks of HIV-related TB involving transmission of multidrug-resistant organisms have been recently reported - reports that are alarming to the public health and medical communities. Multidrug-resistant tuberculosis (MDR-TB) is defined as a tuberculosis infection in which the TB isolate is at least resistant to isoniazid and rifampin, the best available anti-TB drugs. From 1990 through early 1992, the Centers for Disease Control and Prevention (CDC), in collaboration with State and local health departments, investigated outbreaks of MDR-TB in hospitals and correctional facilities in Florida and New York. More than 200 cases of MDR-TB have been identified through these investigations. In these outbreaks, a number of health care workers exposed to patients with MDR-TB have been diagnosed with active disease or have converted their tuberculin skin tests from negative to positive. MDR-TB progresses rapidly in HIV-positive patients, with from 72percent to 89 percent dying within 4 to 16 weeks.

Without aggressive screening and prevention measures, patients and staff in drug treatment centers are at substantial risk of developing active TB and, in some geographic areas, MDR-TB. Drug treatment programs can undertake a number of measures that will reduce this risk. Lessons learned from the MDR-TB outbreak - as well as the recommendations of CDC - provide a guide on what drug treatment programs can do to prevent transmission of both TB and MDR-TB among their patients and staff.

Characteristics of the MDR-TB Outbreaks

How did multidrug-resistant tuberculosis develop? Multiple reasons account for the increased incidence of MDR-TB, but several factors warrant comment. Drug resistance has developed primarily as a result of noncompliance with prescribed anti-TB therapy among patients with active tuberculosis. Many patients were started on appropriate therapy, but adequate and complete medical followup did not occur. Such followup must be consistently carried out to ensure ongoing compliance, completion of therapy, and successful outcomes. Failure to do this left many persons in the community with partially and unsuccessfully treated TB. This unsuccessfully treated population became the source of MDR-TB.

A second factor has been the failure of health care workers to suspect a case of active tuberculosis and rapidly isolate infectious TB patients. Patients who are not recognized as having active TB may expose other persons to the disease both in the hospital and in the community. Among HIV-infected persons, the consequences of failing to recognize possible exposure or active disease have been devastating. In addition, the absence of proper ventilation on hospital wards and in outpatient facilities, as well as in any of a number of other care facilities, has led to the spread of TB in hospitals, prisons, homeless shelters, and other settings.

Delay in Diagnosis

Prompt diagnosis of TB was not always made in the initial MDR-TB outbreaks, because the majority of persons with MDR-TB were HIV-positive, and many had AIDS. The clinical presentation of TB in this population is frequently atypical: lung cavitation may not be present on chest radiographs, and sputums may not be smear-positive for acid-fast bacilli.

In addition, the diagnosis was frequently based only on TB sputum culture results. In most cases, at least 8 weeks had elapsed before culture results were obtained, and even more time had elapsed before drug-susceptibility results became available. Thus even when treatment for TB was started, it usually did not include adequate drugs.

Inadequate Isolation Practices

Patients were not effectively isolated in health care settings. In many cases, doors to rooms of patients known to be infected with TB were not kept closed, health care workers and visitors did not wear masks or used masks improperly, and patients left their rooms without wearing masks. Many hospital isolation rooms did not have negative pressure relative to the hallways (i.e., the direction of air flow was from the isolation room to the hall. The airflow must be from the hall to the isolation room and then outside).

In addition, many HIV-infected persons were clustered on one ward or in large multibed rooms, and the infection was spread from patient to patient in the hospital.

Exposure of Health Care Workers

Because of the failure to recognize, isolate, and adequately treat these MDR - TB cases, a substantial number of health care workers and prison guards who were exposed converted their tuberculin skin tests, indicating recent infection with TB. At least nine of these workers have developed active MDR - TB, and five of them have died.

Prevention Efforts in Health Care Settings

The health care community is now charged with a series of critical tasks, including

- Limiting the spread of TB
- Screening for TB
- Educating the public about TB
- Developing improved strategies for earlier recognition of infection
- Providing supervised and appropriate care
- Making scientific advances that will enable earlier diagnosis as well as better therapies or vaccines

The Centers for Disease Control and Prevention has established guidelines for preventing the transmission of tuberculosis in health care settings. CDC guidelines are shown in [table 1](#). It is mandatory that drug treatment programs become familiar with these guidelines and implement them as necessary in their facilities. Health care facilities unable to comply with these guidelines should transfer any persons with suspected or active tuberculosis to an appropriate health care setting.

Public Health Issues and Implications for the Future

The public health policy regarding diagnosis, isolation, and treatment of tuberculosis in the United States - both now and for the foreseeable future - is undergoing increasing scrutiny and reevaluation. New guidelines are being developed, and over the next few years the approach to issues concerning TB will be changing. There are a number of issues that must be addressed and dealt with at a national level. The following improvements are needed:

- Improved screening methods to detect persons with latent or active TB
- More rapid laboratory diagnosis of active TB
- More rapid drug susceptibility testing to facilitate the prescribing of the most effective combination therapies
- Development of new anti-tuberculosis drugs
- Development of vaccines
- Provision of the means to isolate persons with active tuberculosis who are in health care facilities or other congregate settings (such as correctional facilities) until drug-susceptibility test results are available and until appropriate therapy has been administered for a sufficient period of time to eliminate infectivity
- Provision of the means to ensure prompt treatment with appropriate therapy given in a supervised setting
- Identification of better and/or shorter courses of therapy for preventive therapy of persons with latent infection (i.e., those with a positive purified protein derivative (PPD) or who are infected but are anergic)
- Improved environmental methods to protect potentially exposed persons in living and work places where exposure is of concern
- Better contact tracing and followup
- Education to improve awareness of TB in both health care workers and the general public
- Possible reopening of TB sanatoriums for infected persons for whom adequate and complete therapy will be otherwise difficult.

To limit the spread of MDR-TB and to protect both at-risk patients and health care providers, it is essential that the medical community undertake a concerted and determined campaign to limit the spread of TB, including MDR-TB, as well as HIV infection. This mandate will be one of the principal public health policy challenges for this country during the 1990s.

Chapter 7 - Tuberculosis

Tuberculosis is an infectious disease caused by *Mycobacterium tuberculosis* (MTb). Almost all infection in humans is caused by inhalation of droplet nuclei - infectious particles of aerosolized respiratory secretions coughed up by a person with pulmonary tuberculosis. It may either result in a lifelong silent (latent) infection or in a clinically recognizable disease.

The need for improved detection and treatment of tuberculosis has been significantly increased by the recent outbreaks of multidrug-resistant TB, especially in HIV-infected persons.

Background

Epidemiology

The most common disease is pulmonary tuberculosis; however, extrapulmonary cases do occur. In low-incidence areas such as the United States, most TB cases are attributed to endogenous reactivation of latent

infection; however, significant outbreaks can occur from exposure to a person with active pulmonary tuberculosis.

Over 26,000 cases of TB were reported in 1991, and an estimated 15 million persons in the United States are infected with tubercle bacilli. Incidence is higher in urban settings, among populations with low socioeconomic status, among racial and ethnic minority groups (particularly Hispanics and African Americans), and in medically underserved areas. The risk of TB is higher for persons living in crowded, confined areas, such as residential drug treatment programs, homeless shelters, nursing homes, correctional institutions, migrant worker camps, and long-term care facilities.

Since 1986, the morbidity from TB has been increasing. The increase has occurred mostly in geographic areas and demographic groups with a high incidence of HIV/AIDS cases. The 1991 data also show:

- Twenty-seven percent of cases of active TB occurred in foreign-born persons, compared with 20 percent in 1985. Forty-one percent of these persons had been in the United States less than 5 years.
- Seventy-one percent of reported TB cases were in racial and ethnic minorities.
- Twenty-three percent of cases occurred in the elderly.

Among children with TB, 86 percent of cases occurred in minority groups. Screening for TB should be provided for any child exposed to a person who is or should be receiving treatment for active TB.

Course of the Disease

Most persons who are exposed to a person with active TB and become infected do not develop active disease, but rather have latent, asymptomatic infection for long periods of time. Such patients may benefit from preventive therapy with isoniazid.

Active TB is usually the result of reactivation of latent infection. The symptoms of active disease include fatigue, fever, weight loss, cough, pleuritic chest pains, and hemoptysis. TB is, however, a treatable disease. Treatment requires taking multiple anti-TB drugs for at least 6 to 9 months. The length of treatment may vary, especially in HIV-positive persons. Adherence to the appropriate drug regimen and adequate medical followup are required to complete successful treatment.

Although active TB is usually the result of reactivation of latent infection, health care providers need to be aware that with the increasing numbers of cases of active TB, some patients may present with active disease following recent exposure to a person with active tuberculosis. HIV-infected persons are at particular risk for the development of active TB following a recent exposure. Reactivation of latent TB because of the immunosuppression associated with HIV infection, as well as TB following exposure to a person with active TB, occurs more frequently in the HIV-infected person. There may be rapid progression of the TB infection in such an HIV-infected person.

Program Issues for Drug Treatment Settings

Drug treatment programs funded under the Substance Abuse Prevention and Treatment Block Grant are now required by law to provide tuberculosis services to patients or to ensure that patients receive such services. Section 1924(a) of the ADAMHA Reorganization Act of 1992 (P.L. 102-321) states that

States must require treatment entities receiving funds under grant to make available tuberculosis services to each individual receiving treatment; in the case of an individual denied admission due to lack of capacity, the treatment entity will refer the individual to another provider of tuberculosis services (defined as counseling, testing, treatment).

Transmission of tuberculosis is most effectively reduced by identifying and treating persons with active pulmonary tuberculosis. A full course of isoniazid preventive therapy can reduce the risk of developing active TB in infected persons (i.e., persons with positive skin tests) by more than 90 percent.

Because patients receiving methadone maintenance come to drug treatment centers frequently - often on a daily basis - for extended time periods, methadone maintenance treatment programs are in a unique position to provide daily or twice weekly preventive therapy for the recommended 6- to 12-month period. This preventive service can usually be provided in collaboration with the public health agency.

Screening and Treatment

- In general, all persons entering drug treatment programs should have a Mantoux intradermal skin test for tuberculosis.
- Persons who have a negative skin test for TB, as well as nonreactive control skin tests, should be considered to be anergic. HIV-infected persons are especially at high risk for the development of TB. Any person who fails to react to the TB skin test as well as the skin tests controls and is, therefore, anergic needs to be carefully evaluated to be certain there is no evidence of active TB and to be tested for HIV if the person's HIV status is unknown.
- Persons who have a positive skin test or who have symptoms compatible with TB should be medically evaluated for possible active TB and appropriate treatment or for TB preventive therapy.
- Tuberculin skin tests using the Mantoux method should be repeated annually for patients whose initial skin test is negative.
- Patients with chronic cough (over 3 weeks duration), fever, and other symptoms should be rapidly evaluated for possible active tuberculosis disease. If active tuberculosis is suspected or confirmed, the client should be immediately placed on multiple anti-TB medication and placed in respiratory isolation if institutionalized.

Special Considerations With Infected Patients

Persons with close contact to a person with untreated tuberculosis of the lungs or larynx are at greatest risk of acquiring infection.

The treating physician should inform the case manager in the drug treatment program about patients who are being treated for active TB concerning activity restrictions and possible need for isolation methods to ensure compliance, and about precautions for staff. The need to monitor drug adherence and to determine drug efficacy and potential drug toxicity all highlight the importance of monitoring. For short-term treatment programs, treatment needs to be supervised and aftercare should be provided, including followup with a specific provider and case manager.

Medications for TB preventive therapy and treatment may interact with other drugs, such as methadone and disulfiram (Antabuse), thus requiring careful monitoring and possible dosage adjustment. Rifampin (RIF) may interact with either methadone or disulfiram and may require an increase in methadone dosage. Isoniazid (INH) must be given with care to patients on disulfiram, since such patients can have psychotic episodes or ataxia.

Considerations for Drug Treatment Staff

All health care personnel should have PPD skin tests every 6 to 12 months and at the time of and 3 months after any exposure to a patient with active, untreated TB. The following testing should be done:

- In general, all staff of drug treatment programs should receive a PPD skin test using the Mantoux method when they are first employed.
- Staff with initial negative skin tests should be retested every 6 to 12 months.
- Staff with positive skin tests should receive a prompt medical evaluation for possible active TB, should be considered for TB preventive therapy, and should be evaluated if symptoms of active TB develop.

Staff reading the results of tuberculin skin tests should be trained in the procedure. Training materials on skin testing produced by the Centers for Disease Control and Prevention (CDC) are available through each State health department TB program. See also the section at the end of this chapter, Role of the Health Department, on assistance that the local or State health department may offer to drug treatment centers in setting up a screening program.

Other Program Considerations

Patients Who Refuse Testing

The patient should have the right to refuse screening. However, to protect the safety and health of the other patients and staff, an individual seeking treatment who is thought to have active tuberculosis may be denied admission until it has been medically determined if the patient needs treatment prior to being admitted to the program. A program's drug treatment policies and procedures must be consistent with current local, State, and Federal laws. See section on Access to Treatment in "Legal and Ethical Issues" for further guidance on patients who refuse to be tested.

Local legal guidelines should be consulted for dealing with noncompliant patients who are public health risks, especially given cases of multidrug-resistant TB. (Any patient who is noncompliant with treatment for drug-susceptible or MDR-TB should not be allowed to enter the drug treatment facility; see the following MDR-TB guideline.)

Isolation of Persons With Infectious TB

Prompt, correct drug treatment of an active case of TB is essential. For persons with active or suspected tuberculosis, initiation of treatment as an outpatient may be considered if the person is only mildly ill and is able to care for himself or herself at home. For those with complicated illness or unable to care for themselves, hospitalization is indicated. Hospitalization should be strongly considered for persons with MDR-TB, and the decision not to hospitalize such a patient should be made only after consultation with a physician experienced in caring for patients with MDR-TB. Patients in residential drug treatment programs should be hospitalized unless appropriate respiratory isolation can be provided at the facility.

An active case of TB is usually not communicable once the sputum smears are negative for acid-fast bacilli (AFB) and the patient's symptoms, e.g., cough, have improved. The drug susceptibility of any given TB isolate may not be available, however, for 6 to 12 weeks. If there is any concern that the infected person may have resistant tuberculosis, appropriate respiratory isolation, with hospitalization if it is deemed necessary, should be continued until the person has smear-negative sputum samples or until the drug susceptibilities are known. When the drug susceptibilities are available, the therapy must be reevaluated to be certain that the person is on appropriate therapy and that the patient's adherence can be ensured by placing him or her on directly observed therapy.

General Guidelines

Programs should develop guidelines and procedures for decreasing transmission of tuberculosis through identification, appropriate isolation, and treatment of persons with infectious TB. For general environmental guidelines, refer to the CDC Guidelines in the Summary Statement in [chapter 6](#); see also [chapter 4](#), "Issues for Treatment Program Administrators." There should be adequate ventilation of living and work areas where persons with possible or proven TB congregate. Persons with known infectious TB should not be allowed to enter the living and work areas of a treatment facility until three sputum specimens have been obtained and are smear negative for AFB.

Sputum induction, sputum collection, and aerosolized pentamidine treatments should be done in areas with correct exhaust. If such areas are not available, sputum collection may be done outside the building. Consideration should be given to placing ultraviolet lights in clinic and residential areas where adequate ventilation and air exchange are not possible.

Reporting Procedures

All new cases of active TB must be reported to local/State health departments. Reporting is obligatory in all States. All suspected cases of TB should also be reported to the health department. Any cases of INH- or multidrug-resistant TB should be promptly reported. Contact tracing of all active TB cases must be implemented. Contact tracing is not required for most persons with only a positive PPD. However, in the case of a child with a positive PPD, an investigation should be undertaken to identify the source case.

- Persons with positive skin tests after exposure to MDR-TB should be reported.
- All persons with TB and all suspects, contacts, and others at high risk must have medical services made available by local/State health departments; services to screen for and treat TB should be available to such persons regardless of their ability to pay.
- Prompt attention should be given to any household where contacts of the infectious cases include children or immunosuppressed persons.
- State and local health departments should initiate prompt followup of contacts.

Screening

Screening Criteria

Many persons entering drug treatment programs may have been exposed to TB in the past because of their socioeconomic situation and living conditions. All patients should be screened for tuberculosis on entry into the program; the screening should be done promptly for any person with respiratory problems. It is particularly important to test all injection drug users and persons with HIV infection.

For the asymptomatic person, screening should consist of a Mantoux purified protein derivative (PPD) skin test. For the person with symptoms related to possible active TB, closer clinical followup is necessary.

The Mantoux skin test should be administered to all persons except those with previously documented positive skin tests. A positive skin test indicates prior infection with the tubercle bacillus, but it does not determine whether the person has clinically active tuberculosis.

The HIV status of each person should also be ascertained at the time of entry into the drug treatment program. Any HIV-infected person as well as any person whose HIV status is unknown but who is at risk of HIV infection should have not only the Mantoux skin test but also delayed type hypersensitivity testing with companion anergy testing as part of routine entry screening.

The following persons need prompt and appropriate medical care after the screening for TB:

- Any person with a positive PPD
- Any HIV-infected person with a positive PPD
- Any person with known or suspected active TB
- Any HIV-infected person, person at risk for HIV infection, or person whose HIV status is unknown, who has a negative PPD and no reaction to a companion anergy testing. (See the discussion later in this chapter.)

Periodic screening for TB and HIV infection should be continued during and after the drug treatment program. All persons in treatment programs should have, at a minimum, a yearly PPD and HIV test after the initial screening. This screening is an attempt to slow the spread of TB and HIV as well as to provide care to any individual needing it. It should be remembered that a patient with untreated or inadequately treated TB is a significant hazard for both staff and other patients.

Screening Methods and Tests

A medical history should be obtained from all patients. A tuberculin skin test should be applied unless there is adequate documentation available that the patient had a positive skin test in the past.

Persons with a positive skin test or symptoms suggesting TB should have a chest radiograph and confirmatory microbiological tests, in addition to the tuberculin skin test and medical history. Other tests may be necessary to exclude extrapulmonary TB.

An HIV-infected person, or a person at risk for HIV infection whose HIV status is not known, should have a chest x-ray to screen for tuberculosis if that person has a positive skin test or is anergic. In cases of possible extrapulmonary tuberculosis, additional tests may be necessary to make the diagnosis.

Tuberculin Skin Test

The Mantoux tuberculin skin test is the most sensitive screening test and should be the skin test used. A multiple-puncture test (Tine test) should not be used as a screening test.

The Mantoux technique for the tuberculin skin test requires the intradermal injection of 0.1 ml of purified protein derivative (PPD) tuberculin containing 5 tuberculin units (TU). The skin test must be read after 48 to 72 hours by a person qualified to interpret and record the results.

A person with a previously documented positive PPD should not be retested.

For persons who have received bacillus Calmette-Gurin (BCG) vaccination, a positive tuberculin skin test usually indicates infection with tuberculosis. Such persons should be evaluated for preventive therapy with isoniazid.

The interpretation of a test as positive or negative (a negative test is not necessarily nonsignificant) is dependent on the exposure history and underlying medical condition of each individual tested.

A negative skin test does not rule out tuberculosis disease or infection. The skin test results alone should not be used to exclude the possibility of active TB in persons for whom the diagnosis is being considered.

See [table 1](#) for interpretation of tuberculosis skin test results.

Interpretation of Nonreactive PPD Test Results and Anergy Testing in HIV-Positive Persons

The following points should be considered when interpreting tests for HIV-positive patients:

- HIV-positive persons may have a false-negative PPD because of impairment or absence of the delayed type hypersensitivity (DTH) response seen with HIV infection.
- The CDC recommends DTH anergy testing at the time of PPD screening in HIV-positive persons at risk for tuberculosis, and in persons of unknown HIV status who are at risk for HIV infection and tuberculosis.
- Companion anergy testing should be done using Candida, mumps, or tetanus antigens (two of the three).
- Reactivity to any of the antigens implies a "working" immune system. In conjunction with a negative PPD, these results would indicate a true negative or no TB infection. Any reaction with induration to the mumps, tetanus, or Candida skin tests means that the person is not anergic. For the PPD tuberculin skin test, a reaction of less than 5 mm implies that a person is not anergic. At the same time,

it is not considered a positive skin test when screening for TB. No reaction to the antigens, including PPD, indicates anergy. *Skin testing will not detect latent TB in an anergic person.*

- The CDC recommends consideration of preventive therapy in HIV-positive persons who are anergic, have negative PPD skin tests and are known contacts of infectious TB patients, or are from groups, such as persons in addiction treatment programs, in which the prevalence of TB infection is 10 percent or more. *If the contact has MDR-TB, preventive therapy should be administered to an HIV-infected person. Recommendations for the appropriate preventive therapy for an HIV-positive person exposed to a person with MDR-TB should be made by a physician knowledgeable about this subject and the drug susceptibility of the MDR-TB isolates in that area.*

The anergic HIV-positive person should be clinically evaluated for evidence of active tuberculosis. If there is no evidence of active disease, such persons should be given preventive therapy if they have had possible exposure to TB in the past.

Medical History

The medical history should cover the signs and symptoms of tuberculosis: persistent cough, hemoptysis, weight loss, loss of appetite, fever, chills, night sweats, pleuritic chest pain, or unexplained lymphadenopathy.

If the patient is HIV-positive, there should be a review of risk factors associated with HIV infection.

Known contact with a person with active tuberculosis is a risk factor. Socioeconomic risk factors include residence in a long-term care facility; homelessness; living in a shelter or correctional facility; injection drug use; crack use; immigration from an area endemic for TB, such as Haiti, Africa, Southeast Asia, South and Central America, Caribbean Basin; having moved from an urban setting where possible exposure to TB may have occurred.

Chest Radiograph

At the time of enrollment in a drug treatment program, the following persons should have a chest x-ray:

- Persons with a history of a positive PPD
- Persons with a positive PPD at screening
- Persons with a negative screening PPD whose medical history/physical examination is consistent with possible active tuberculosis infection (e.g., cough of 3 or more weeks duration, pleuritic chest pain, fatigue, weight loss, fever, night sweats, loss of appetite), regardless of the skin test reaction
- HIV-infected persons who are anergic (i.e., had a negative PPD and negative controls)
- Persons at high risk for HIV infection whose HIV status is unknown and who are anergic (i.e., have a negative screening PPD as well as negative controls)

Confirmatory Microbiological Tests

For persons with a medical history/physical examination and a chest x-ray consistent with possible active tuberculosis, the principal way to diagnose pulmonary tuberculosis is the smear and culture examination of three sputum specimens collected on different days.

A positive sputum culture with *Mycobacterium tuberculosis* gives a definitive diagnosis of tuberculosis. If a smear is reported to reveal acid-fast bacilli (AFB), a person should be referred for immediate medical care.

Medical Management Issues

The following persons should be medically evaluated for the presence of active TB infection (that is, they should have a medical history/physical examination and a chest x-ray):

- Any person with a positive PPD
- Any anergic HIV-positive person
- Any person with symptoms suggestive of active TB

Indications for Preventive Therapy

Persons with a positive skin test in the following groups, *regardless of age*, should receive preventive therapy unless there are medical contraindications.

- HIV-infected persons (5 mm or greater)
- Close contacts of infectious newly diagnosed TB cases (5 mm or greater)
- Recent PPD skin test converters (10 mm or greater increase within a 2-year period if less than 35 years old; 15 mm or greater increase for those 35 years and older)
- Previously untreated or inadequately treated persons with abnormal chest x-rays (5 mm or greater)
- Injection drug users (10 mm or greater)
- Persons with medical conditions that increase the risk of developing active TB. (See medical conditions listing in screening section.) (10mm or greater)

Persons with positive skin tests in the following high-risk groups who are *less than 35 years of age* should receive preventive therapy:

- Foreign-born persons from high-prevalence countries (Africa, Southeast Asia, Latin America) (10 mm or greater)
- Low-income populations, including low-income minorities at high risk (African Americans, Hispanics, and Native Americans) (10 mm or greater)
- Residents of long-term care facilities (including prisons, nursing homes, correctional institutions) (10 mm or greater)
- Persons not at high risk for tuberculosis with a PPD 15 mm or greater if they are less than 35 years old

INH preventive therapy should be considered for the anergic HIV-positive patient if he or she has been exposed to TB or is from a population where the prevalence of TB infection is greater than 10 percent.

Administering Preventive Therapy

With no evidence of active TB (after medical history/physical examination and chest x-ray), the person requiring preventive treatment should be treated with isoniazid (INH) unless there are medical contraindications. A full course of preventive therapy ([see table 2](#)) reduces the risk of developing active TB in infected persons by up to 90 percent.

Contraindications for INH Preventive Therapy

INH preventive therapy is contraindicated for

- Persons with previous INH-associated hepatic disease
- Persons with a history of an allergic reaction to INH
- Acute liver disease of any etiology; hepatitis B surface antigen (HBsAg) positivity is not a contraindication *unless* associated with chronic active hepatitis.

INH preventive therapy should be given with special precautions to persons with the following conditions:

- Age greater than 35 years (due to toxicity of INH)
- Concurrent use of other medications on a long-term basis

- Daily use of alcohol or excessive intermittent alcohol consumption
- Alcoholism
- Persons on disulfiram (Antabuse), who may have psychotic episodes or ataxia if given INH
- Diabetes
- Pregnancy
- Current known chronic liver disease
- Presence of peripheral neuropathy

For anyone receiving INH preventive therapy, INH should be discontinued if the liver function tests (LFTs) increase three to five times above normal, consistent with possible drug-induced hepatitis. Persons taking INH should be advised to seek medical attention if they develop any symptoms suggestive of possible hepatitis, such as jaundice, fatigue, weakness, malaise, anorexia, nausea, or vomiting.

For a person unable to tolerate INH, prophylaxis of non-MDR-TB with rifampin (600 mg by mouth daily) may be given for 6 to 12 months.

Monitoring of INH Preventive Therapy

Monthly monitoring of persons on INH preventive therapy should be done for the following conditions:

- Symptoms consistent with those of liver damage or other toxicities: Anorexia, jaundice, fatigue, or weakness lasting greater than 3 days; persistent numbness or tingling in hands or feet. If nausea or vomiting occurs, the patient should promptly stop taking the drug and seek medical care.
- Signs of active liver damage: Persistently dark urine, icterus, jaundice, rash, elevated temperature for 3 days or more, abdominal pain or tenderness.

For asymptomatic persons under 35 years of age, a baseline liver function test should be obtained; the liver function test should be repeated periodically, since the drug-using population is at a higher risk for liver disease.

For persons older than 35 years of age, transaminase liver function tests (LFTs) should be done at the initiation of therapy and periodically during the course of therapy. If LFTs are greater than three to five times normal, or the patient has symptoms of hepatitis, INH should be discontinued.

All injection drug users and alcoholics - regardless of age - should have baseline LFTs.

Followup

All persons should have yearly PPD skin tests. Any person with a positive PPD who develops symptoms consistent with active TB should have a medical examination and a chest x-ray.

Treatment of Persons With Active Tuberculosis

All persons with active TB must be treated; they must have close medical followup while on anti-TB medications and upon completion of therapy. Persons with positive AFB sputum smears or persons presumed to have extrapulmonary TB should be given anti-TB medications prior to TB culture results.

Regardless of the frequency of therapy (whether it is daily, twice a week, or three times a week), it should be directly observed. The reason for this is that directly observed therapy increases compliance.

CDC regimen options for the initial treatment of active TB in HIV-negative and HIV-positive persons are shown in [table 3](#). [Table 4](#) gives dosage recommendations for the initial treatment of TB among children and adults. The current recommendations are that four drugs be given as initial treatment except in areas where the rate of

INH resistance is less than 4 percent. In areas with less than 4 percent INH resistance reported, treatment may be initiated with only three drugs.

Drug Toxicities and Interactions

Rifampin (RIF) may accelerate the clearance of drugs metabolized in the liver, including methadone, disulfiram (Antabuse), anticonvulsants (e.g., Dilantin), oral hypoglycemics, coumarin, estrogen, birth control pills, digitalis, ketoconazole, glucocorticoids, and cyclosporine. Rifampin will turn body fluids and soft contact lenses orange. Women taking oral contraceptives while on rifampin are at risk for becoming pregnant because of increased metabolism of the oral contraceptives.

INH may cause hepatitis, peripheral neuropathy, and an increase in the level of phenytoin (Dilantin). Phenytoin levels should be monitored. INH decreases the metabolism of phenytoin and disulfiram (Antabuse).

Pyrazinamide (PZA) may cause an elevated uric acid although acute gout is rare. Patients who are asymptomatic with an elevated uric acid should continue PZA. PZA may also be hepatotoxic.

Ethambutol (SUPB) may cause a skin rash and optic neuritis. Patients placed on SUPB should report any changes in their vision. Visual acuity and red/green color perception should be tested every 4 to 6 weeks.

Streptomycin (SM) should be used with caution in any persons who have impaired renal function and in the elderly. The renal toxicity is increased in persons with a dosage of greater than 1 gram per day. In addition, all patients should have a baseline audiogram because of the ototoxicity of SM, and repeat exams should be done periodically. SM should not be given to pregnant women as it may cause congenital deafness.

One must remember that all of these regimens are for INH-susceptible TB; however, the patient is placed on therapy pending the TB culture susceptibility results, which may take several weeks to months. The current CDC recommendations for treatment of TB are that the initial therapy should include four drugs, except in areas where INH resistance is less than 4 percent; in these areas, initial therapy with three drugs is recommended ([see table 3](#)). Further, if a patient is on empiric treatment but not improving, consideration should be given to prescribing two or more additional drugs. A single drug should never be added to a failing regimen. Many of these management decisions will have to be made prior to having any drug susceptibility test results and will require consultation with a physician knowledgeable about these management issues.

Special Considerations for Methadone Recipients and Pregnant Women

Methadone Recipients

Drugs for prophylaxis or treatment of tuberculosis should be given with methadone whenever possible.

Persons on methadone maintenance and rifampin may require an increased methadone dose if the person has signs and symptoms of drug withdrawal.

Pregnant Women

TB skin testing and anergy testing are safe during pregnancy.

Pregnant women with active tuberculosis or who are suspected of having active TB should be referred to a specialist. Treatment should not be delayed.

An HIV-positive pregnant woman with a positive TB skin test and no clinical evidence of active TB should receive INH prophylaxis for 12 months. An HIV-positive pregnant woman at risk for TB who is anergic and has

no clinical evidence of active TB should receive INH prophylaxis for 12 months. The prophylaxis should be initiated at the end of the first trimester of pregnancy.

An HIV-positive pregnant woman who has recently been exposed to a person with infectious TB should be given INH prophylaxis regardless of the stage of pregnancy. An HIV-negative pregnant woman who has recently been exposed to a person with infectious TB and has a positive skin test should be given INH prophylaxis during pregnancy. The drug, however, should not be initiated until the end of the first trimester.

Any pregnant woman with radiographic evidence of possible past TB that was never treated should be given 1 year of INH prophylaxis. Treatment should begin during pregnancy, but not until the end of the first trimester. For other pregnant women who have positive skin tests, INH preventive therapy should be delayed until after delivery.

There is an increased incidence of active TB in the postpartum period in infected women who were not given preventive therapy in the past.

Role of the Health Department

The State health department can aid the drug treatment program by establishing working relationships with staff who are providing health-care services to high-risk populations. The health department will assist the drug treatment program in developing and instituting appropriate screening programs. Specifically, health departments should

- Assist in training staff to perform, read, and record tuberculin skin tests; to evaluate positive tuberculin reactors for clinical tuberculosis and preventive therapy; to provide preventive therapy and monitor for compliance and adverse drug reactions; and to educate clients regarding the need for preventive therapy. Some health departments certify staff who complete this training. CDC-produced staff training and patient education materials are available through each State health department TB program.
- Identify medical consultants who can assist with diagnosing and managing tuberculosis cases and suspects and, as needed, managing persons on preventive therapy.
- Assist with arrangements, upon request, for referring and following persons on preventive therapy who develop clinical tuberculosis or adverse drug reactions.
- Assist in evaluating screening programs.
- Recommend continuation or discontinuation of screening programs on the basis of their effectiveness.
- Conduct contact investigation on each new TB case or suspect case reported.

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Chapter 8 - Multidrug-Resistant Tuberculosis

The emergence of multidrug-resistant tuberculosis (MDR-TB) as a major health problem over the past several years has prompted the Centers for Disease Control and Prevention (CDC) to closely reexamine tuberculosis policy in the United States. A series of guidelines have been issued by the CDC since 1991 concerning MDR-TB in the United States. The following statement on MDR-TB is extracted from CDC's "National Action Plan To Combat Multidrug-Resistant Tuberculosis" (p.7).

Recently, drug-resistant TB has become a serious concern. In a recent survey in New York City, 33 percent of cases had organisms resistant to at least one drug, and 19 percent had organisms resistant to both isoniazid and rifampin, the two most effective drugs available for treating TB. When organisms are resistant to both isoniazid and rifampin, the course of treatment increases from 6 months to 18-24 months, and the cure rate decreases from nearly 100 percent to less than 60 percent.

Drug-resistant TB is not limited to New York. CDC recently conducted a nationwide survey of drug resistance among all TB cases provisionally reported during the first 3 months of 1991. Overall, 14.4 percent of these cases tested had organisms resistant to at least one antituberculosis drug, and 3.3 percent had organisms resistant to both isoniazid and rifampin. Furthermore, the drug resistance problem appears to be worsening. For example, from 1982 to 1986, only 0.5 percent of new cases were resistant to both isoniazid and rifampin; by 1991, this proportion had increased to about 3.1 percent. Among recurrent cases, 3.0 percent were resistant to both drugs during 1982-1986, but in 1991 this proportion had more than doubled, to 6.9 percent.

Against this background of increasing numbers of TB cases and increasing numbers of drug-resistant cases, a serious new phenomenon has appeared: outbreaks of multidrug-resistant (MDR) TB in institutional settings. From 1990 through early 1992, CDC, in collaboration with State and local health departments, investigated seven outbreaks of MDR-TB in hospitals and correctional facilities in Florida and New York. To date, these outbreaks have included more than 200 MDR cases. Virtually all these cases had organisms resistant to both isoniazid and rifampin, and some had organisms resistant to seven antituberculosis drugs. Most of the patients in these outbreaks were infected with HIV. Mortality among patients with MDR-TB in these outbreaks was high, ranging from 72 percent to 89 percent, and the median interval between TB diagnosis and death was short, from 4 to 16 weeks. In addition to hospitalized patients and inmates, transmission of MDR-TB to health-care workers and prison guards has also been documented; at least nine of these workers have developed active MDR-TB, and five of them have died.

The rise in drug-resistant TB and the outbreaks of MDR-TB are a manifestation of serious underlying problems in the health-care infrastructure in the United States. An increasing proportion of TB cases is occurring among persons who were born in another country or who are homeless, who have substance abuse problems or mental illness, or who have other socioeconomic or medical problems, such as HIV infection, that make compliance with therapy difficult. Yet, at the same time that the number and complexity of TB cases have been increasing, fiscal constraints in government at all levels have led to cutbacks in many TB control programs. As a result, health departments have not had adequate resources to place all potentially noncompliant patients on directly observed therapy or to bring outbreaks under control. There have been shortages of antituberculosis drugs and significant increases in their costs. Screening and preventive therapy have not been offered consistently to many groups at high risk of TB (e.g., HIV-infected persons) because of limited resources.

Program Issues for Drug Treatment Settings

The following are special considerations and recommendations for residential and nonresidential methadone and other drug treatment programs regarding MDR-TB.

Screening and Treatment or Referral

In setting up a screening and treatment or referral program, the following medical components need to be included:

- All patients entering drug treatment programs should be screened for TB at entry to the program and, especially in high TB incidence areas, should have a followup PPD skin test every 6 to 12 months.
- All employees in methadone treatment and other drug treatment programs should have a PPD skin test every 6 to 12 months.
- Any patient or employee who is exposed to a case of TB should have a TB skin test at the time of exposure and again 12 weeks later.

Special Considerations With Infected Patients

Careful consideration should be given to the question of whether or not hospitalization is appropriate for a person with MDR-TB. There are conditions under which a person with known or suspected MDR-TB does not need to be hospitalized.

If the person is medically stable and has a stable home situation in which young children or immunocompromised persons will not be exposed, and is on effective therapy with good clinical and bacteriologic regimens, hospitalization is not required. All therapy should be directly observed for anyone who is not hospitalized, and close medical followup is mandatory.

If the person is not medically stable and does not have an adequate home situation, hospitalization is appropriate.

To ensure compliance with TB therapy, all patients should be observed as they take their medications (for example, with the daily methadone dose).

Other Program Considerations

Noncompliant Patients

Any patient being treated for MDR-TB or receiving prophylaxis for latent MDR-TB who is noncompliant with that treatment should be reported to the local health department and should not be allowed to enter the drug treatment facility.

Isolation of Infected or Possibly Infected Persons

Any patient in a methadone treatment program, whether residential or nonresidential, who develops any clinical signs or symptoms of TB must be immediately referred for medical treatment. In areas with MDR-TB, all such persons must be placed in respiratory isolation (that is, acid-fast bacilli isolation) in a hospital setting. Until the drug-susceptibility tests are available or until the AFB smear is negative (if initially the AFB smear was positive), the patient must remain in isolation. The person should be considered as potentially infectious until three sequential smears are negative for TB organisms.

Any patient in a residential facility who has a cough or other symptoms of possible TB should be removed from a dormitory-type setting to an infirmary or other isolated area until a medically qualified person has evaluated the patient for possible TB.

General Guidelines

Programs should develop guidelines and procedures to decrease transmission of the TB bacillus by means of environmental precautions and appropriate ventilation measures. In any clinic area where patients are coughing, sneezing, or being asked to cough to give a sputum sample, the ventilation must be adequate. If adequate ventilation (negative pressure room with a minimum of six air exchanges per hour) is not available, these persons should not stay in the clinic area; clinics may need to have patients step outdoors and obtain sputum specimens from them there.

Both residential and nonresidential drug treatment facilities should consider installing and maintaining ultraviolet lights; use of such lights could play a role in killing the TB bacillus in certain areas of the treatment facility. CDC recommendations for ultraviolet light are in Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings (p. 15). The recommendations state in part:

The decision to use UV lamps should be made on a case-by-case basis. If UV lamps are used, applicable safety guidelines should be followed . . . UV lamps are not recommended for use in small rooms or booths where nebulizing devices will be used. UV units installed in ducts should not be used to recirculate air from a tuberculosis isolation room back into the general circulation.

Reporting

All cases of active MDR-TB or cases of conversion to a positive skin test after exposure to MDR-TB should be reported to local/State health departments for followup. Close contact tracing, especially of household contacts including children, must be done promptly and properly.

Screening

See the guidelines for screening in the TB section.

Medical Management of MDR-TB

The following persons should be evaluated for the presence of active MDR-TB as well as non-MDR-TB (that is, they should have a medical history/ physical examination, and chest x-ray):

- Any person with a positive PPD
- Any anergic HIV-positive person

Preventive Treatment of MDR-TB

With no evidence of active MDR-TB (after history/ physical examination and chest x-ray), the person requiring preventive therapy for MDR-TB may be placed on preventive therapy. Such therapy needs to be based on the drug-susceptibility testing of prior cases of MDR-TB in that geographic area. The correct preventive therapy after exposure to MDR-TB is not known.

Note: The proper preventive therapy for INH/RIF-resistant or additional drug-resistant TB is not INH alone. In some cases, for those who would normally require preventive treatment, the treatment of choice may be close medical followup rather than preventive therapy with multiple drugs.

HIV-Infected Persons

For the HIV-infected, anergic person, again, the correct preventive therapy after known exposure to MDR-TB is not known. However, these persons should not only have close medical followup, but they should also be given prophylaxis based on discussion with local experts.

The appropriate drug combination for preventive treatment of MDR-TB must be determined by consulting with the local health department, the CDC, and others expert in treating TB. [Table 1](#) defines the likelihood of exposure to MDR-TB. Figure 1 shows the CDC outline of the approach to use in selecting drug regimens for preventive therapy and for those at low to low-intermediate, and intermediate to high risk.

The duration of multidrug preventive therapy is 12 months for HIV-infected persons and at least 6 months for others.

In general, close medical followup will be required for at least 2 years, regardless of whether patients are or are not given multidrug preventive therapy. Medical examinations and chest radiographs should be provided as follows:

- For HIV-infected persons; every 3 months for 2 years
- For HIV-negative, otherwise healthy persons; every 6 months for 2 years

Treatment of Persons With Active MDR-TB

Isolation and Infection Control

All persons with presumed or documented MDR-TB should be placed in respiratory isolation in a hospital setting unless they are medically stable and the home situation is adequate, as discussed previously. Persons who are hospitalized should remain in strict respiratory isolation until three AFB smear-negative sputums, taken on three successive days, have been obtained. After three smear-negative sputums have been obtained, the person may be removed from respiratory isolation provided that no other signs or symptoms of ongoing pulmonary TB are present.

Persons with positive AFB sputum smears should be placed on directly observed anti-TB therapy pending the results of the sputum culture. For persons with positive AFB sputum smears or negative AFB sputum smears but presumed pulmonary tuberculosis, all anti-TB medications should be given as directly observed therapy pending the results of the sputum cultures. Likewise, for persons with presumed extrapulmonary tuberculosis with AFB positive or negative tissue smears, all therapy should be directly observed while culture results are awaited.

Treatment

Following are recommendations for treatment of possible active MDR-TB while awaiting results of susceptibility testing. Consultation with a physician experienced in treating MDR-TB in the local area is advisable.

1. Prior to TB culture-susceptibility results, a minimum of a four- to five-drug anti-TB regimen should be initiated. There are currently no standard recommendations for the treatment of possible active MDR-TB while results of isolate susceptibility testing are being awaited. The initial treatment regimen will reflect the known susceptibility patterns of prior resistant isolates in that geographic region or, if known, of the contact case. Consultation with a physician experienced in treating MDR-TB in the local geographic area is necessary and is strongly advised.
2. The length of therapy has not been determined for infections caused by MDR-TB.
3. When drug-susceptibility results are available, the treatment regimen must be reevaluated and changed if needed.

4. For persons failing to respond to initial therapy, additional drugs may need to be added prior to obtaining the drug susceptibility results.

Compliance With Therapy

To ensure compliance with TB therapy, the patient should take the medication under supervised conditions, even in the hospital. Once the patient is discharged from the hospital, the medications must be taken in a supervised setting (for example, with the daily methadone dose). The pills should be swallowed in front of the person who dispenses the drugs to the patient.

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Chapter 9 - Human Immunodeficiency Virus and the Acquired Immunodeficiency Syndrome

The second decade of the acquired immunodeficiency syndrome (AIDS) epidemic began in 1991. In May 1981, five cases of *Pneumocystis carinii* pneumonia were reported to the Centers for Disease Control (CDC). During that same period, the CDC was receiving reports of Kaposi's sarcoma in homosexual men; by late 1981, more than 100 cases had been reported. In September 1982, the CDC defined this new syndrome as the acquired immunodeficiency syndrome. In 1983, the human immunodeficiency virus type 1 (HIV-1) was isolated from persons with AIDS.

Since that time, the AIDS epidemic has become worldwide despite significant advances by the medical and scientific community in understanding the pathogenesis of HIV, recognizing and treating the related opportunistic infections, and developing drugs to slow the progression of HIV disease. Despite the best available medical care, there is disease progression in most infected persons. Ultimately, most infected persons will develop an AIDS-defining opportunistic infection or malignancy. HIV infection and AIDS will lead to premature death for the great majority of infected persons.

Daunting projections are being made by the World Health Organization and others concerning the worldwide impact of the AIDS pandemic in the 1990s. It is estimated that between 30 and 110 million persons will be infected with HIV by the year 2000. In Africa and Asia, the future toll of this epidemic is difficult to comprehend. It is estimated that there will be more than 10 million orphans in sub-Saharan Africa alone.

Over time, HIV-infected persons will experience progression of their HIV infection with all of the concomitant medical, social, and economic problems. It is essential that the late stage HIV/AIDS patient have medical, social, and psychological support. Persons with more advanced HIV disease face the need for hospitalization; the loss of employment; the decreased capacity to care for the daily needs of themselves and their dependents; the issues of loss of autonomy, dying, and death; and the needs of dependents, especially infants and children. For the foreseeable future, the delivery of this support to the ever increasing number of HIV-infected persons - men, women, and children - will challenge and strain the health care and social service systems of this country, especially in large inner cities.

Background

Infection with the human immunodeficiency virus (HIV) is usually associated with a progressive disease process. The clinical spectrum ranges from asymptomatic infection to the acquired immunodeficiency syndrome (AIDS). Many persons with HIV infection are unaware that they are infected. Although some HIV-

infected persons will remain asymptomatic for 10 or more years, most will ultimately develop some symptoms related to this infection.

HIV is spread from person to person by three well-recognized routes. The overwhelming majority of cases are transmitted sexually through either heterosexual or male-to-male intimate sexual contact where there is exposure to body fluids such as semen, blood, and vaginal or cervical secretions. Other cases are spread by parenteral transmission (either through transfusion of contaminated blood or blood products or through injection with a blood-contaminated needle or syringe) or by perinatal transmission, which may occur in utero, intrapartum, or through breastfeeding. Although these transmission routes are well understood, successful intervention to prevent the spread of HIV infection remains a major worldwide public health issue.

Epidemiology

As of June 1992, there were more than 480,000 reported cases of AIDS worldwide and an estimated 10 million persons infected with HIV. In the United States, it is estimated that between 1 million and 1.2 million persons are infected with HIV; 230,000 of these persons have AIDS and more than 171,890 have died. [Table 1](#) shows the characteristics of persons diagnosed with AIDS in the United States in 1992. It is apparent from this table that nearly one third (31.9 percent) of cases are attributable to injection drug use, either alone or combined with male single-sex/bisexual sexual contacts. Among women with AIDS, 71 percent of all cases are linked directly or indirectly to injection drug use. Also, 70 percent of the pediatric cases resulting from maternal-infant transmission are related to the mother's exposure to HIV through injection drug use or through sex with an injection drug user.

During 1991, the proportion of new AIDS cases increased most among women, among persons infected via heterosexual contact, among persons living in the South, and among African Americans and Hispanics. In 1991, 49 percent of all AIDS cases occurred in non-Hispanic whites, 32 percent in African Americans, and 18 percent in Hispanics. African Americans accounted for 45 percent of HIV cases attributed to injection drug use, and Hispanics for 26 percent. Both male and female adolescents - particularly young African-American women - are at increasing risk of HIV infection, especially through unprotected heterosexual intercourse.

Course of the Disease

Once infected with HIV, a person may have a relatively asymptomatic period when there are few if any clinical manifestations of the infection. HIV itself infects primarily the CD4 lymphocytes, monocytes, and macrophages, all of which are vital to the body's ability to prevent serious infections or malignancies. HIV has the ability not only to kill these cells or decrease their function but also to remain latent in these and other cells. Over time, most persons infected with HIV will have disease progression marked by clinical manifestations as well as a progressive decline in the number of CD4 cells.

Any HIV-infected person benefits from ongoing and regular medical care with the institution of antiretroviral therapy and preventive prophylaxis when appropriate.

Program Issues for Drug Treatment Settings

The prevention and treatment of HIV/AIDS is a matter of serious concern to drug treatment programs in terms of the health of their patients and staff and of helping to protect the public health of the community at large. Injection drug users are a group at special risk of HIV infection. Approximately 32 percent of all adult and adolescent AIDS cases are related to injection drug use.

Because of this high risk of HIV infection among injection drug users, control of AIDS is inevitably tied to the availability of drug treatment and to other prevention services targeted to injection drug users. The city of New York alone has an estimated 200,000 injection drug users, 50 percent of whom are HIV-infected. Yet New York City has only 38,000 publicly funded drug treatment slots. On a national basis, the National Institute on Drug Abuse recently estimated that more than 100,000 persons are currently on waiting lists for drug treatment programs.

Screening and Medical Management

It is recommended that drug treatment clinics undertake the following steps to provide for the prevention and diagnosis of HIV among their patients, and to enable patients to receive medical treatment as early in the disease process as possible.

- Encourage all patients entering drug treatment to be screened for HIV infection at the time of entry to the program or as soon as feasible if the patient initially refuses testing. The Consensus Panel recommends that consent should be obtained before any testing begins. Informed consent is required for HIV testing in some jurisdictions. See Issues Concerning HIV Testing in "Legal and Ethical Issues," this volume, for more information on this topic.
- Provide periodic followup screening and risk-reduction counseling for patients who are HIV-negative.
- Provide counseling to patients both before and after the HIV screening test, with counseling done in a private and confidential setting.
- Ensure that patients with HIV infection receive appropriate medical care, including immunizations and scheduled medical followup examinations and treatment.

Ensure that patients with HIV infection receive psychosocial evaluation and referral for services, including employment, social services, legal assistance, and transportation, if needed.

Provide training for program staff if the drug treatment program plans to conduct HIV counseling and testing on site instead of referring patients out for testing. For information on training, see "Issues for Counselors."

Other Program Considerations

HIV Education

Ongoing education should be provided for staff and for all persons enrolled in the drug treatment program. This education needs to take into consideration the different cultural backgrounds as well as the age and level of education of the persons involved. The educational program should include comprehensive coverage of the following subjects:

- Modes of transmission and manifestations of HIV infection
- Reduction of risk behavior - both sexual and related to drug use
- Explicit and clear instructions concerning safer sex, including help to both men and women on use of condoms and safer sex practices, as well as the role of abstinence
- Discussion of pregnancy and HIV, including the risk of transmission to the fetus or newborn
- Sharing needles, syringes, drug vials, and cookers can transmit infection, since any part of this equipment may be contaminated. The patient should be given instructions about safer usage of needles, syringes, and other drug paraphernalia, including refraining from sharing needles and the dangers of purchasing presumably "clean" needles on the street. The limitations of bleach should be stressed. Users should be told that cleaning syringes, needles, or other drug paraphernalia with bleach may not kill the HIV virus. Treatment centers should contact the Centers for Disease Control and Prevention frequently to obtain updated guidelines on the disinfection of drug injection equipment and should keep drug users up to date on the guidelines. See [appendix G](#) for a further discussion on bleach.
- The impact of continued drug, alcohol, and tobacco use on the immune system and HIV infection

Universal Precautions

Instituting universal precautions in the workplace is mandatory, especially in areas where blood is drawn and handled. Immediate medical followup must be made available to anyone who sustains a needlestick injury or has cutaneous or mucous membrane exposure to blood or other potentially infectious body fluids. Issues concerning potential exposure to HIV-1 and viral hepatitis B and C must be addressed.

Reporting Procedures

State laws vary. All States require the reporting of AIDS cases, as defined by the Centers for Disease Control and Prevention, to health departments. A growing number of States also specifically or implicitly require reporting on HIV-positive test results. For further information on issues of confidentiality, anonymous and confidential testing, and partner notification, refer to the chapter "[Legal and Ethical Issues](#)."

HIV Counseling and Testing

Indicators for HIV Counseling and Testing

All persons entering drug treatment programs should have a blood test for HIV infection at the time of entry into the program or as soon as feasible if the person initially refuses testing. If HIV negative after the initial screening, the person should be tested periodically thereafter. Behavioral and other factors placing people at particular risk for HIV infection are listed in [table 2](#).

General Clinical Manifestations

General clinical manifestations often associated with HIV infection are shown in [table 3](#). Persons with a history of tuberculosis, viral hepatitis B or C, or any sexually transmitted disease should be counseled and tested for HIV. An HIV-infected person is more likely than a non-HIV-infected person to develop serious bacterial infections, especially pneumonia and tuberculosis. Any patient with such a history should receive HIV counseling and testing.

Serologic Testing, Interpretation, and Counseling

It is important to choose a reliable laboratory that is experienced with HIV testing. If there are any concerns about the reliability of a test, repeat it at a different laboratory.

Serologic testing for HIV consists of the following tests:

- The initial screening test is the enzyme immunoassay (EIA). If this test is reactive, the test is repeated.
- If the repeat EIA is reactive (that is, positive), a supplemental test, the Western blot, is performed. The Western blot detects antibodies to specific HIV proteins. Certain bands must be present to be considered positive, as follows:
 - Reactive Western blot: any two of three major diagnostic bands (p-24, gp-41, gp-120/160).
 - Indeterminate Western blot: presence of one or more viral-specific bands that fail to meet the criteria for reactive Western blot.
 - Nonreactive Western blot: no bands.
- A positive HIV-1 test: a positive EIA and reactive Western blot mean that the person is infected and infectious.

Detectable antibody usually develops within 3 months after infection but takes longer in some people. Although a nonreactive antibody test usually means that a person is not infected, nonreactive antibody tests cannot rule out infection from a recent exposure (i.e., within 3 to 6 months of testing in most cases).

For a person at risk for HIV-1 infection, the tests should be repeated in 3 months if the EIA is negative or if the Western blot is indeterminate or nonreactive. If the tests are still indeterminate at 3 months, the tests should be repeated at 6 months. Very rarely, infected persons may not become antibody positive for 12 months or longer. If the person continues to engage in high-risk behavior or to have any clinical evidence of possible HIV infection, the tests should be repeated every 6 to 12 months thereafter.

In rare instances, additional serologic testing, such as the immunofluorescent antibody assay, HIV viral culture, or polymerase chain reaction (PCR) may be appropriate.

Counseling at the Time of HIV Testing

Pre-Test Counseling

At the time of HIV serologic testing, pre-test counseling by a qualified counselor should be available. Testing and counseling should be conducted in a private setting and in a professional and confidential manner. The counseling should include

- A client-centered risk assessment that will assist the person to arrive at a self-perception of risk and development of a risk-reduction plan. (See the 1993 CDC publication, *Recommendations for HIV Testing Services*, listed in the Sources.)
- A discussion of the implications of a positive, indeterminate, or negative test
- The psychosocial and medical significance of a positive test
- An assessment of the appropriateness of the response of the person being tested
- A discussion of the need for the person to notify his or her sexual or injection drug-using partners of a positive test result, so that they may be tested and avail themselves of medical care as needed
- The need to practice safer sex and not share syringes, needles, or other drug paraphernalia

Post-Test Counseling

The post-test counseling should be done at the time that the HIV test results are discussed. The HIV test results should not be given over the phone or by letter, but should be discussed in person in a private setting. The confidentiality of the person should be respected.

HIV-positive patients should be told their test results by a person who is able to discuss the medical, psychological, and social implications of HIV infection. Test results for an HIV-negative patient should be transmitted by a person who can explain the need to reduce or modify high-risk practices to eliminate potential exposure. Appropriate psychosocial and medical followup should be arranged at that time for an HIV-infected person or at-risk person with negative or equivocal test results. (For further information, see the section Counseling the HIV-Positive Patient in the chapter ["Issues for Counselors."](#))

Certain factors are thought to increase the infectiousness of the HIV-infected person. Patients with HIV need to be aware of these factors, which include

- Advanced HIV disease
- Genital/rectal/oral ulcer disease
- Low CD4 lymphocyte count

Increasing the likelihood of sustained behavior change may require that post-test counseling include multiple sessions. Counseling guides or formats are available through State health department HIV-prevention programs and are usually made available as part of training in this process. Help with counseling is also available from the National Clearinghouse on AIDS.

Management of the HIV-Infected Person

For the HIV-infected person, access to both appropriate medical care and to appropriate psychosocial support is imperative. Recent studies have demonstrated the benefit of the early use of antiviral therapy for HIV and of prophylaxis for certain opportunistic infections, even in asymptomatic patients. The availability of such therapy underscores the importance of identifying persons who are infected and of providing early intervention services.

Clinical Presentation and Classification of HIV Infection

HIV infection progresses through a continuum from the acute initial infection ultimately to an AIDS-defining illness and death.

Acute HIV Infection

One to six weeks after the initial infection, many infected persons experience a nonspecific flu-like febrile illness that lasts several days to weeks. The clinical features may include fever, rash, fatigue, generalized lymphadenopathy, malaise, muscle aches, joint pain, headache, pharyngitis, photosensitivity, and encephalitis. Symptoms may be masked by drug use. Many patients may have only one or several of these symptoms; most patients will recall none of these symptoms. Many patients will not attribute these symptoms to acute HIV infection.

Asymptomatic Stage

After acute infection, most persons have no signs or symptoms of HIV infection for a number of years (median about 10 years). Fauci and his colleagues and Haase and his colleagues have recently confirmed that the HIV virus is sequestered in lymphoid tissue during the acute phase and then in the clinically latent phase of infection. While most patients remain asymptomatic, it now appears that there is significant impairment of the immune system during this stage of illness. (These new studies suggest that it may be possible and preferable to some day treat HIV early on, rather than after the immune system shows signs of deterioration.) During this asymptomatic phase, there is, however, a progressive decline in the CD4 lymphocyte count, which is detectable only through lab testing.

Persistent Generalized Lymphadenopathy Stage

During this stage, most patients will have no significant findings on physical examination other than enlarged lymph nodes. Some patients will have several groups of enlarged lymph nodes. The lymph nodes most frequently involved are the axillary, inguinal, posterior cervical, preauricular, epitrochlear, postauricular, and femoral nodes.

Later Stages of HIV Infection

As HIV infection progresses and the CD4 lymphocyte cell count decreases, patients will experience more complications. Any organ system may be involved.

Definition of HIV Infection and of AIDS

A person who has a positive screening test for HIV is both infected and infectious. In August 1987, the Centers for Disease Control and Prevention (CDC) established criteria for defining AIDS in adult, adolescent, and pediatric (less than 13 years of age) cases. In 1993, CDC revised and expanded the case definition for AIDS. The following changes were made in the AIDS surveillance case definition for adults and children 13 years of age and older:

- The case definition was expanded to include all HIV-infected persons with a CD4 count of less than 200 cells/mm³ or a CD4 lymphocyte percentage of total lymphocytes of less than 14.
- Three new clinical conditions were added as AIDS-defining illnesses: pulmonary tuberculosis, recurrent pneumonia (two or more episodes in a 1-year period), and invasive cervical cancer.

The 23 clinical conditions in the AIDS surveillance case definition published in 1987 are retained. [Table 4](#) shows the CDC case definition for adults and adolescents with AIDS. The Centers for Disease Control and

Prevention considers that a person has AIDS if that person has certain specific secondary opportunistic infections or malignancies or fulfills the criteria for HIV encephalopathy or HIV wasting syndrome.

Definition of HIV Encephalopathy and HIV Wasting Syndrome

HIV encephalopathy is defined as being a progressive decline in cognitive function, memory, and behavior, as well as other changes on neurologic examination and neuropsychiatric assessment. The HIV wasting syndrome is defined as involuntary weight loss of more than 10 percent below baseline weight coupled with the presence of fever for more than 1 month or diarrhea persisting for more than 1 month. Diagnosis of these diseases is made presumptively, after laboratory confirmation of HIV infection.

Clinical Management

Complete History

A health care provider knowledgeable about HIV infection should conduct a complete history and physical examination. The history should include previous medical illnesses; family history; allergies and adverse drug reactions; current drugs and medications; use of drugs including alcohol, tobacco, and habitual or illicit drugs; psychosocial history; sexual history; and review of symptoms.

Physical and Mental Status Examinations

Patients should receive a complete physical examination and a mental status examination. For women, the physical examination should include a pelvic examination, Pap smear, breast examination, and evaluation for STDs.

Baseline Laboratory Studies

Laboratory studies should include

- Complete blood count (CBC)
- Differential blood count
- Platelet count
- Serum electrolytes
- Blood urea nitrogen (BUN) and creatinine
- Liver function tests: alkaline phosphatase, aminotransferases (AST, ALT)
- Serum lactate dehydrogenase (LDH)
- Serologic tests for syphilis (VDRL, FTA-ABS)
- Hepatitis B and C serology
- Skin test for tuberculosis (PPD) with anergy controls
- Total CD4 lymphocyte count

Immunizations

Since diseases may be more severe in persons with HIV infection, the CDC recommends that all persons at risk for HIV have their history of vaccination and immune status evaluated for diseases for which vaccines are available (pneumococcal pneumonia, influenza, diphtheria, tetanus, measles, mumps, rubella, *Haemophilus influenza* type B, and hepatitis B).

For maximum benefit to those with HIV, vaccines should be administered as soon as possible after HIV is diagnosed. Many patients with suppressed CD4+ cell counts have a diminished antibody response. Live-virus

vaccines such as the oral polio vaccine and bacillus Calmette-Gurin (BCG) for tuberculosis prevention are contraindicated. Adults with HIV should receive the following vaccines:

- Pneumococcal vaccine if not previously administered; revaccination after 6 years
- Influenza vaccine during the flu season each fall
- Hepatitis B vaccine if there is no serologic evidence of prior infection or if the person was not previously vaccinated. One to 6 months after the vaccine series is completed, antibody to HBsAg (anti-HBs) should be measured. If anti-HBs is less than 10 mIU/mL, revaccination with one or more doses should be offered.
- Tetanus booster every 10 years with Td (tetanus/diphtheria toxoids, absorbed).

For patients with HIV, *Haemophilus influenza* type B conjugate vaccine should also be considered. All adults born in or after 1957 should have evidence of immunity to measles: documentation of measles vaccine after the first birthday; serologic evidence of a protective titer; or history of measles with physician's documentation. Although measles, mumps, and rubella vaccines are live attenuated vaccines, they may be given to HIV-infected persons. For an HIV-infected person born in or after 1957 or for an HIV-infected person born before 1957 without evidence of immunity to measles, the measles, mumps, rubella (MMR) vaccine should be considered.

For nonpregnant HIV-infected women of childbearing potential, measles, mumps, and rubella vaccine should be administered, especially to women born in or after 1957. Such vaccination is not needed for women who have a dated record of at least one dose of live measles vaccine on or after their first birthday, of physician-diagnosed disease, or of laboratory evidence of immunity.

Followup on Initial Physical Examination and Laboratory Studies

Any significant abnormal findings from the review of symptoms or physical examination should be appropriately followed up.

Laboratory abnormalities should be addressed. The results of the CD4-lymphocyte count will frequently serve as the basis for followup. Patients with HIV infection, especially drug users, are at risk for bacterial infections such as pneumonia, bacteremia, and tuberculosis even before the CD4 count falls below 200 cells/mm³. When the CD4 count is less than 200, HIV-infected persons are at increased risk of developing opportunistic infections, especially pneumocystis pneumonia. More serious complications usually occur with a CD4 count of less than 100. The greatest risk for death occurs when the CD4 count is less than 50.

1. CD4 greater than 800 - schedule followup in 6 months.
2. CD4 500 to 800 - schedule a 3-month followup.
3. CD4 less than 500 but greater than 200 with a patient who is (a) symptomatic, institute antiretroviral therapy; (b) asymptomatic, consider instituting antiretroviral therapy or consider continued observation and monitoring for clinical or laboratory evidence of disease progression. When disease progression occurs, antiretroviral therapy should be instituted. For persons with persistent and unexplained fever (greater than 100 F) for 2 weeks or oropharyngeal candidiasis, primary prophylaxis to prevent *Pneumocystis carinii* pneumonia (PCP) should be started. Similarly, for persons with a prior episode of PCP, secondary prophylaxis is indicated.
4. CD4 less than 200 - institute antiretroviral therapy as well as primary prophylaxis to prevent PCP. Schedule monthly to bimonthly clinic visits. At any time, should a patient's condition change, that patient may require a more thorough evaluation. Close followup and evaluation need to be provided, especially if there is physical or mental deterioration.

Antiretroviral Therapy

Preliminary recommendations to guide health care providers concerning the use of the antiretroviral drugs zidovudine (AZT), didanosine (ddI), and zalcitabine (ddC) in adults in the early, intermediate, and late stages of HIV disease have been issued by an expert panel ([National Institute of Allergy and Infectious Diseases 1993](#)).

A decision to intervene with antiretroviral drugs should be made by the health care provider and the patient; the choice to accept or decline antiretroviral therapy ultimately rests with the patient, according to the panel. The intervention should include primary medical care - with management of the patient's overall health status - and should provide emotional and psychological support. Current information on clinical trials is available from the AIDS Clinical Trials Information Service, 1-800-TRIALS-A.

The following is excerpted from the panel's preliminary recommendations:

The recommendations for patients who have never before received antiretroviral therapy are:

- For patients without symptoms whose CD4+ T cell counts are above or equal to 500 cells/mm³, the panel recommends continued observation, and clinical and immunological monitoring, (measurement of CD4+ T cell counts) every 6 months.
- For patients without symptoms whose CD4+ T cell counts are between 200 to 500 cells/mm³ and who are stable over time, the panel recommends consideration of the following two options:
 1. initiation of antiretroviral therapy;
 2. continued observation and monitoring for clinical or laboratory evidence of deterioration, at which point antiretroviral therapy should be initiated.
- For patients with CD4+ T cell counts between 200 to 500 cells/mm³ who present with symptoms related to HIV disease, the panel recommends starting antiretroviral therapy.

When choosing an initial antiretroviral therapy:

- Use AZT as first-line therapy in patients who have received no prior antiretroviral therapy. The recommended dose is 600 mg/day in divided doses.
- The recommendation to initiate therapy with AZT applies to patients with or without symptoms, with CD4+ T cell counts between 200 to 500 cells/mm³ or below 200 cells/mm³, or to patients with severe AIDS-Related Complex or AIDS regardless of their CD4+ T cell counts.
- Combination therapy with AZT and ddI or AZT and ddC also may be considered, although clinical trials have not conclusively demonstrated clinical benefit to date.

On changing initial therapy in patients who are tolerating an initial antiretroviral therapy:

- In patients tolerating initial therapy, the panel recommends continuing AZT for patients who appear to be stable with CD4+ T cell counts above 300 cells/mm³.
- For patients who have CD4+ T cell counts below 300 cells/mm³, the panel recommends consideration of two options:
 1. continuing AZT; or
 2. changing to ddI.

The panel notes that the strongest data supporting a change in therapy to ddI were seen in patients who had been on AZT for 4 months or longer (median duration of 13 months prior to AZT).

For patients who are intolerant to AZT or who experience progression of disease despite AZT therapy:

- In patients with CD4+ T cell counts between 200 to 500 cells/mm³ and 50 to 200 cells/mm³ who are intolerant of AZT, the panel recommends switching to ddI monotherapy. For AZT intolerant patients with CD4+ T cell counts of less than 50 cells/mm³, the panel recommends switching to ddI or ddC monotherapy. Another option includes discontinuing antiretroviral therapy [for persons with CD4+ T cell counts of less than 50 cells/mm³].
- For patients with CD4+ T cell counts between 200 to 500 cells/mm³ and 50 to 200 cells/mm³ who show signs of clinical progression, the panel recommends initiating an alternative antiretroviral regimen. Options include monotherapy, for example with ddI, or initiation of combination therapy by adding a second agent, either ddI or ddC.
- For patients with CD4+ T cell counts below 50 cells/mm³ and who have evidence of disease progression, the panel recommends switching to an alternative monotherapy, either ddI or ddC.

Other options include combination therapy.

- For patients with CD4+ T cell counts above 500 cells/mm³ who are taking AZT but experience intolerance, the panel recommends discontinuation of therapy.

[Table 5](#) gives dosages and side effects of treatment of the antiretroviral drugs AZT, ddI, and ddC.

Prophylaxis of Opportunistic Infections

In addition to antiretroviral therapy, prophylaxis is currently recommended by the U.S. Public Health Service for the prevention of two AIDS-related opportunistic infections, *Pneumocystis carinii* pneumonia (PCP) and disseminated infection caused by *Mycobacterium avium* complex (MAC).

It is estimated that up to 85 percent of HIV-infected persons will develop PCP with over 65,000 cases occurring each year in this country. Without prophylaxis, persons with a CD4 count below 200 cells/mm³ have an 8.4 percent risk of developing PCP within 6 months. Even with prompt diagnosis and appropriate treatment, with the first episode of a mild case of PCP, up to 10 percent of patients will die. For persons with moderate to severe PCP, reported mortality rates are even higher. Appropriate lifelong prophylaxis to prevent PCP should be instituted for any HIV-infected persons with a CD4 count less than 200 cells/mm³; for patients with persistent and unexplained fever (greater than 100 F) for 2 weeks or oropharyngeal candidiasis regardless of CD4 count; or for persons who have had a prior episode of PCP. [Table 6](#) gives the doses and more common side effects of the drugs available for PCP prophylaxis.

Persons with acute PCP have primarily respiratory symptoms, with the majority having cough, fever, dyspnea on exertion, and fatigue. The typical chest x-ray in PCP shows diffuse interstitial infiltrates in both lung fields. Any HIV-infected person with respiratory symptoms should be evaluated for PCP as well as tuberculosis and other pulmonary infections; appropriate treatment should be started if the clinical and laboratory findings are consistent with acute PCP.

Mycobacterium avium complex (MAC) causes disseminated disease in up to 40 percent of patients with HIV infection. The majority of cases of disseminated MAC occur in persons with a CD4 count of less than 75 cells/mm³. Patients with advanced HIV infection who develop disseminated MAC experience fever, night sweats, weight loss, abdominal pain, and diarrhea. The main laboratory abnormalities are anemia and an elevated alkaline phosphatase. Patients with disseminated MAC die sooner than similar patients without disseminated MAC. The diagnosis of disseminated MAC is dependent on the isolation of MAC in a blood culture or from a sterile body tissue or fluid.

Given the severity of symptoms associated with disseminated MAC and the increased mortality, the U.S. Public Health Service has issued recommendations for the prophylaxis and treatment of disseminated MAC. The current recommendation is that all HIV-infected persons with a CD4 count less than 100 cells/mm³ receive 300 mg rifabutin orally daily for life unless disseminated MAC develops. Prior to beginning rifabutin prophylaxis, all patients must be evaluated to ensure that they do not have active MAC or *M. tuberculosis* (Mtb). The medical evaluation should include a chest x-ray and tuberculin skin test. If there is any concern that the patient has active MAC disease or active Mtb, rifabutin prophylaxis should not be given. If, after placing a patient on rifabutin, there is concern that the patient may have active MAC or Mtb, the rifabutin should be discontinued and appropriate clinical and laboratory followup obtained. [Table 7](#) summarizes the recommended prophylaxis to prevent disseminated MAC.

Any patient who shows signs and symptoms of a serious opportunistic infection, such as those shown in [table 8](#), or possible tuberculosis, should be referred for prompt medical evaluation. Opportunistic infections or malignancy suggest advanced HIV disease and the need for immediate referral, prompt evaluation, and treatment.

Access to Care

Because complications may develop at any time, provisions for appropriate care, including emergency care, after-hours care, and specialty consultation, must be made available for all patients. Drug treatment programs should have established relationships with infectious disease specialists, early intervention clinics, comprehensive care centers, and hospitals.

Psychosocial Management

Evaluation

At the time of diagnosis of HIV infection, all HIV-infected persons should be evaluated by a social worker or other person qualified to do a psychosocial evaluation. The evaluation should address the following issues:

- Understanding of the implications of HIV infection
- Family, community, and other support systems
- Employment and economic circumstances
- Adequacy of housing, food, medical care
- Ability of patient to obtain prescribed medications
- Access to a support group, buddy system, or other social support system
- Eligibility for food stamps, housing subsidy, Medicare, Medicaid, Social Security benefits, etc., as appropriate
- Arrangement of child care for children of HIV-infected parents, especially mothers, so that they can obtain medical care and meet other needs
- Assessment of transportation needs

For further information, see Counseling the HIV-Positive Patient in the chapter ["Issues for Counselors."](#)

Education and Counseling

Instruction should be provided in the reduction of at-risk behavior. Culturally appropriate HIV/AIDS education and counseling need to reinforce changed behavior and safer sex. For example, both male and female patients may need instruction in how to use a condom and how to negotiate safer sex practices with partner(s). Patients with HIV need to understand the impact of continued drug use on the immune system and on HIV infection. Patients should be told that harm-reduction initiatives and reduction of drug use have the potential to improve the quality and duration of life. For further information, see Risk Reduction in the chapter ["Issues for Counselors."](#)

Medical Management With Special Groups

HIV-Infected Women of Childbearing Age

Transmission of HIV from an infected mother to her unborn fetus or to her infant before or during delivery can occur. If an HIV-infected woman becomes pregnant, she needs to be informed of these risks. She should also be told that if she has more advanced HIV infection, the risk of HIV transmission may be greater than one third. For an HIV-infected pregnant woman, nondirective counseling on pregnancy options should be offered.

In addition, should an HIV-infected mother have a baby, she should be advised that even if the infant was not infected at birth, there is a risk of transmission from breastmilk of the HIV virus to the infant. The current recommendation in the United States is that an HIV-infected woman not breastfeed her infant. In addition, there is a risk of transmitting HIV infection to an infant if the mother was infected after delivery of the baby during the time she was breastfeeding that child.

The HIV status of any children should be determined and testing, if needed, should be arranged. Infected or at-risk children should be referred for care. The parent needs to be informed that the results of HIV testing in infants and babies may not be reliable up to 15 months of age and additional HIV testing of the child may be necessary.

Uninfected Partners

Some drug treatment patients who are HIV negative may be the sexual or injection drug-sharing partners of persons who are HIV positive. In addition to education and counseling about risk-reduction measures, these patients also need to be aware of personal factors that may increase their risk of contracting HIV infection. Factors associated with increased risk of infection for the uninfected sexual partner include

- Incorrect and inconsistent use of condoms
- Presence of genital/rectal/oral ulcers
- Receptive anal intercourse
- Sex during menses
- Rectal/vaginal bleeding or trauma

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Chapter 10 - Syphilis

Syphilis is a systemic infection that has been known since the 15th century. It is caused by the spirochete *Treponema pallidum* and is almost always spread by contact with infectious lesions during sexual intercourse.

Background

If left untreated, syphilis goes through several phases.

Symptoms of primary syphilis usually occur within 3 weeks of the initial infection. Secondary syphilis occurs within 4 to 10 weeks following exposure. Tertiary syphilis typically appears 2 to 20 years after the initial infection. Latent syphilis is the term applied to the interval between stages - primary, secondary, or tertiary - that have disease manifestations. Having sexual contact with a person with early (primary or secondary phase) syphilis, particularly contact with a primary chancre, carries the greatest risk of infection. About one third of those having sexual contact with persons with early syphilis will be infected.

Transmission of infection may occur after sharing needles with injection drug users who are infected with syphilis, although this would be unusual. Donated blood and blood products, however, are routinely screened for syphilis, and the risk of infection by transfusion is essentially nil.

Congenital syphilis is of increasing concern, given the rise in the incidence of syphilis in women of childbearing age. The fetus may be infected if the mother has untreated syphilis. The risk to the unborn fetus is greatest when the infection of the mother is recent.

Epidemiology

With the introduction of penicillin and improved public health measures, the number of reported cases of syphilis in the United States declined steadily from the 1940s to the 1970s. In the late 1970s and early 1980s, the incidence of syphilis increased, with a disproportionate rise among men who have sex with other men. At the beginning of the AIDS epidemic, the number of cases of syphilis declined. In 1985, however, the incidence of syphilis in heterosexual men and women began to rise. From 1985 to 1990, the incidence of primary and secondary syphilis increased 75 percent, with over 50,000 reported cases. Today the Centers for Disease Control and Prevention estimates that there are 120,000 cases of syphilis detected each year, of which 40,000 to 50,000 are infectious.

The greatest rise in syphilis has been among young African-American men and women in the inner cities and is related to the use of illegal drugs, especially crack cocaine. The use of crack cocaine has been shown to be associated with increased sexual activity with multiple sexual partners, and the concomitant spread of syphilis.

Course of the Disease

The natural course of untreated syphilis goes through several well-described phases. After the initial infection, usually by sexual contact with a syphilitic lesion, there is an incubation period of about 3 weeks before the symptoms of primary syphilis develop. The primary lesion of syphilis is a chancre that occurs at the site of inoculation, most often the genitals. This chancre is usually painless and may be inconsequential. Chancres heal in a matter of weeks even without treatment.

The disseminated or secondary stage of syphilis occurs 4 to 10 weeks after the initial exposure. Secondary syphilis may have multiple manifestations, including skin rash; constitutional symptoms; central nervous system involvement with headache, meningismus, meningitis, and other complications; and, more rarely, hepatitis and renal abnormalities.

Latent syphilis is that stage of the disease in which the serologic tests for syphilis are positive, but there are no clinical manifestations of infection. Tertiary syphilis may affect any organ system and occurs 2 years to many years after infection. The major manifestations of tertiary syphilis are benign latent syphilis with gummata, syphilitic aortitis, or neurosyphilis.

A pregnant woman infected with syphilis may have a stillbirth or spontaneous abortion. An infant born with congenital syphilis may have multiple complications, including characteristic congenital defects. In the HIV-infected person, syphilis infection may be more virulent and more likely to invade the central nervous system.

Program Issues for Drug Treatment Settings

The high correlation between drug use and syphilis makes it especially important to identify and treat the disease among persons enrolled in drug treatment programs. Syphilis, fortunately, is responsive to treatment with antibiotics. Screening and treatment should be accompanied by appropriate counseling and medical followup.

In setting up a screening and treatment or referral program, the following components need to be included:

- Screening should be provided for all persons entering drug treatment programs.
- Screening should be repeated every year if at-risk behavior continues, or earlier if signs and symptoms suggestive of syphilis infection occur.

Special Considerations With Infected Patients

Drug treatment programs need to be aware of the following issues with regard to patients infected with syphilis:

- Infected mothers should be advised to have their young children screened for undetected congenital syphilis if they were not screened at birth.
- Persons known to be infected with syphilis should be counseled regarding safer sex practices. The correct use of condoms will decrease the likelihood of exposure to a genital/rectal syphilis lesion. For further information on condom use, see the chapter "Counseling Issues."
- Testing for HIV infection should be encouraged. Syphilis may increase the risk for infection with and transmission of HIV.

Other Program Considerations

Clients Who Refuse Testing

A person has the right to refuse screening and treatment for syphilis. Clients who refuse testing should not be excluded from treatment programs because of presumed or actual infection. They should be counseled and treated as if they were potentially infectious to others.

Universal Precautions

Staff should employ universal precautions when coming in contact with body fluids, regardless of the documented status of a person. Precautions are appropriate for patients with primary and secondary syphilis, and for infants with early congenital syphilis. Precautions are unnecessary for latent and tertiary disease.

Mandatory Reporting Procedures

All States mandate that cases of syphilis be reported. Reporting should be done promptly in accordance with local/State health department regulations to facilitate contact tracing. Contact tracing and subsequent interviewing by health authorities are fundamental for control of the disease.

Screening

Indicators for Screening

Drug treatment facilities need to screen all patients for syphilis. In particular, persons should be screened who have a current diagnosis or past history of gonorrhea, genital herpes, HIV infection, or any other sexually transmitted disease. Also, screening is indicated for any person with a genital chancre, skin rash characteristic of secondary syphilis, or lymphadenopathy.

[Table 1](#) presents behavioral risk factors for syphilis.

Screening Techniques

Preliminary Screening Tests

Serologic tests for screening include the following quantitative nontreponemal or reaginic tests:

- Venereal Disease Research Laboratory (VDRL)
- Rapid-plasma-reagin (RPR)
- Automated reagin test (ART)

If the preliminary screening test is positive, a confirmatory test is done.

Confirmatory Tests

Specific antitreponemal antibody tests:

- Fluorescent treponemal antibody absorption (FTA-ABS)
- *T. pallidum* microhemagglutination (MHA-TP)

Darkfield Examination for Syphilis

If examined by darkfield microscopy, treponemes may be seen in fluid obtained from a chancre, the lesion of primary syphilis or condyloma lata, lesions occurring during secondary syphilis. If the treponemes are seen, this is diagnostic of syphilis.

This technique will not be available, however, in most drug treatment programs and is not a screening test to determine prior infection with syphilis.

Special Considerations in Screening Tests

Test results are dependent on the stage of the infection ([see table 2](#)).

Interpretation of Test Results

- The serologic tests may be negative in the incubation period, in primary syphilis, and in untreated syphilis of many years' duration.
- A false-positive screening test for syphilis (VDRL or RPR) may be associated with many conditions and is usually reactive at low titers of less than 1:8.
- False-positive tests may occur with tuberculosis, injection drug use, pregnancy, viral hepatitis, chronic liver disease, and bacterial endocarditis. When the VDRL or RPR is a false positive, the FTA-ABS or MHA-TP will be nonreactive in most cases.
- Any person with positive serologic tests for syphilis should be advised to have an HIV test and asked about signs and symptoms of other sexually transmitted diseases, such as gonorrhea and genital herpes.

Frequency of Screening

Serologic screening should be repeated every year if at-risk behavior continues, or sooner if a person has signs or symptoms suggestive of syphilis infection.

Medical Management Issues

The clinical stage of the syphilis infection dictates the medical management, treatment, and followup. The different clinical categories of syphilis infection are

- Early syphilis: primary and secondary syphilis and early latent syphilis of less than 1-year duration
- Late latent syphilis: syphilis of more than 1-year duration or of unknown duration
- Neurosyphilis
- Congenital syphilis
- Syphilis in pregnancy
- Syphilis and HIV infection

Early Syphilis

Primary Syphilis

The main symptom of primary syphilis is a painless ulcer, a chancre, that appears at the site of exposure 14 to 21 days after that exposure. A primary chancre usually occurs in the genital, perirectal, or oral cavity. If untreated, the lesion heals on its own in 3 to 8 weeks.

Secondary Syphilis

Secondary syphilis occurs 4 to 10 weeks after the primary chancre. The classical presentation is that of a disseminated, symmetric, papular rash that involves the trunk, palms, and soles. The infection is systemic with generalized lymphadenopathy and, less commonly, headaches, malaise, fever, hepatitis, and arthritis, as well as kidney, eye, and central nervous system involvement. Even without treatment, the patient's symptoms will improve.

Early Latent Syphilis of Less Than 1-Year Duration

Many patients will not remember their initial infection and the length of time since exposure may not be known.

Clinical Management and Followup for Early Syphilis

Table 3 presents the recommended treatment regimen for early syphilis.

Followup for Early Syphilis

- Patients should be examined and serologic tests should be repeated at 3 months and 6 months.
- For primary and secondary syphilis, the VDRL or RPR should decline by fourfold 3 months after treatment (e.g., VDRL of 1:64 to 1:16; 1:8 to 1:2).
- For early latent syphilis, the titer should decrease by fourfold 6 months after treatment.
- If the titer has not dropped appropriately or if signs and symptoms persist, the patient should be referred to a physician for a spinal tap and possible retreatment.

Late Latent Syphilis of More Than 1-Year Duration or of Unknown Duration

If a patient has a positive syphilis serology and the length of infection is unknown, the patient should be treated for late latent syphilis.

Clinical Management and Followup for Late Latent Syphilis

The patient with late latent syphilis should have a lumbar puncture to examine the cerebrospinal fluid in the following circumstances: if neurological signs or symptoms are present; the initial treatment was unsuccessful; or the VDRL is greater than or equal to 1:32.

Table 4 presents the recommended treatment for late latent syphilis.

In addition, HIV-infected persons and penicillin-allergic patients may require a lumbar puncture to examine the cerebrospinal fluid (CSF). CSF findings in a patient with neurosyphilis include an elevated white count, primarily lymphocytes, and an elevated CSF protein. The VDRL may or may not be reactive. If the findings on examination of the CSF are consistent with neurosyphilis, the patient should be treated with high-dose intravenous penicillin. A person with a penicillin allergy and central nervous system syphilis should be hospitalized and desensitized to penicillin.

Followup of Late Latent Syphilis. The VDRL or RPR should be repeated after treatment at 6 months and 12 months. The treatment was adequate if the titer declines by fourfold and the patient has no signs or symptoms of syphilis. If not, the patient may have been reinfected or the patient will need to be evaluated for possible neurosyphilis.

Neurosyphilis

Any patient, with or without concurrent HIV infection, should be evaluated for possible neurosyphilis. The cerebrospinal fluid should be examined if the patient has cranial nerve abnormalities such as an ocular palsy, deafness, nystagmus, vertigo, or stroke symptoms; headaches; meningitis; or personality change.

Clinical Management and Followup of Neurosyphilis

Table 5 presents the recommended treatment regimen for neurosyphilis.

Followup of Neurosyphilis. After treatment for neurosyphilis, the patient should have a repeat lumbar puncture every 6 months or until the cell count is normal. Retreatment is indicated if the cell count fails to decline after 2 years.

Congenital Syphilis

The fetus or infant of a woman with untreated or inadequately treated syphilis is at risk for congenital syphilis. Approximately a third of the mothers whose infants or children have syphilis received no prenatal care. No infant should be released from a hospital until the syphilis serology of the mother is known. Likewise, older infants and children of a woman with syphilis, especially latent syphilis, should be examined by a pediatrician.

The clinical signs of congenital syphilis are diverse. Infants and children who have congenital syphilis should receive appropriate medical care and followup. Without treatment, a child may at some time in the future develop neurosyphilis.

Medical Management With Special Groups

With HIV Co-Infection

There is a considerable amount of controversy surrounding the appropriate management of syphilis in the HIV-infected person. In the HIV-infected person, the development of neurosyphilis is more frequent. Neurosyphilis may present as meningitis, optic neuritis, or deafness, as well as cranial nerve palsies with meningitis in some cases.

Screening

The serologic test results for syphilis may be different in the HIV-infected person, with a higher than expected RPR in early HIV and an undetectable or lower RPR in late HIV infection. While serologic tests are reliable, the interpretation of test results in HIV-infected persons should include these considerations:

- The presence of a primary syphilitic chancre increases the risk for infection with and transmission of HIV.
- In most HIV-infected persons, the serologic tests for syphilis are reliable and accurate.
- Most HIV-infected persons will respond to appropriate treatment for syphilis, and the serologic responses after treatment will be similar to those of non-HIV-infected persons.
- Mean syphilis titers may be higher in HIV-infected than in noninfected persons.

Treatment

For most HIV-infected persons, the course of syphilis is the same as for those who are HIV-negative. Penicillin is the preferred drug to treat syphilis in HIV-infected persons. If an HIV-infected person has a known penicillin allergy, desensitization may be appropriate, because of concerns about the efficacy of doxycycline or other drugs in treating syphilis in HIV-infected persons.

In an HIV-infected person with no neurologic deficits, it is not always necessary to do a lumbar puncture. At this time, some physicians recommend that an HIV-infected person with a reactive serum VDRL undergo a lumbar puncture and subsequent treatment for neurosyphilis with high-dose penicillin if there are abnormalities in the cerebrospinal fluid (CSF), even if the CSF-VDRL is nonreactive. The presence of an elevated white blood cell count or protein in the CSF, with no other explanation, may be caused by CSF syphilis; therefore, treatment is considered appropriate. There is controversy concerning these recommendations, and expert medical consultation would be appropriate if there are questions concerning the diagnosis of neurosyphilis in an HIV-infected person.

[Table 6](#) presents alternative treatment regimens for syphilis in persons co-infected with HIV.

Followup

After appropriate treatment, patients should be followed clinically and serologically with a VDRL/RPR at 1, 2, 3, 6, 9, and 12 months after treatment. After 6 months, the VDRL/RPR should decrease by fourfold. If the titer rises or does not decrease, the patient should have a lumbar puncture for examination of the cerebrospinal fluid and retreatment if appropriate.

With Pregnancy

Screening

All pregnant women should be screened for syphilis during their initial prenatal care. If no prenatal care is provided, the woman should have serologic screening for syphilis at the time of delivery. In populations at high risk for syphilis, the screening should be done at the initial prenatal visit, at the end of the second trimester, and at the time of delivery.

Treatment

A pregnant woman with untreated syphilis should be treated with penicillin at the dosage appropriate for the stage of infection as outlined above (early, early latent, or late latent). Tetracycline and doxycycline are contraindicated during pregnancy. Erythromycin is associated with treatment failures in pregnancy.

For a pregnant woman with a true penicillin allergy, the appropriate treatment of syphilis is to hospitalize and desensitize her to penicillin prior to treatment.

Any woman treated for syphilis in the second half of pregnancy is at risk for a Jarisch-Herxheimer reaction, with possible premature labor or fetal distress.

The HIV-infected pregnant woman should be treated according to the guidelines for any HIV-infected person. Doxycycline and tetracycline, however, are contraindicated.

Followup

Monthly followup is mandatory for a pregnant woman after being treated for syphilis. The followup should include a clinical examination. Retreatment may be necessary for some pregnant women.

Note: Treatment recommendations for pregnant women are especially subject to change.

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Chapter 11 - Introduction to Viral Hepatitis

Most cases of viral hepatitis in humans are caused by four viruses. These include hepatitis B virus, hepatitis C virus, hepatitis A virus, and hepatitis D virus, or delta-hepatitis. There are, however, distinct differences in these viral agents in terms of their epidemiologic, immunologic, and clinical characteristics. For drug users, hepatitis viruses B and C are the agents of major concern. This is because the major risk of infection is by bloodborne transmission, especially via shared needles, syringes, and other drug paraphernalia. There is also a risk of developing chronic hepatitis, and even - over time - the risk of developing hepatocellular carcinoma (liver cancer).

Drug treatment programs should routinely screen for hepatitis B. Hepatitis C should be tested for in all persons known to have used injection drugs. Liver enzymes should also be measured. Additional testing needs to be done as follows:

- Serologic testing for hepatitis A should be done only in persons with acute hepatitis.
- Serologic testing for hepatitis D virus should be done only in persons with known hepatitis B virus infection who have chronic hepatitis and are hepatitis B surface antigen (HBsAg) positive, since the presence of serologic evidence of infection with hepatitis D does not alter the clinical followup or therapeutic intervention from that of a patient with chronic HBV infection.

Chapter 12 - Viral Hepatitis B

Hepatitis B virus (HBV) is a double-stranded deoxyribonucleic acid (DNA) virus. HBV is transmitted by three main mechanisms: (1) percutaneous inoculation (such as by sharing of contaminated needles, accidental

needlesticks, or contacting a contaminated blood mucous membrane, or passing through a skin break); (2) intimate contact (especially sexual); and (3) perinatal spread from an infected mother to her newborn infant. Hepatitis B surface antigen (HBsAg) has been isolated in all body fluids. Blood and blood products, saliva, semen, and vaginal fluids are infectious.

Since November 1981, a vaccine for hepatitis B has been available in the United States. Despite the availability of a vaccine, the reported incidence of hepatitis B increased by 37 percent from 1979 to 1989. The majority of these new cases occurred among injection drug users and heterosexuals with multiple partners. Since 1989, the reported incidence of hepatitis B has declined about 40 percent. Only 25 percent of the new cases of HBV infection in the United States each year have acute icteric disease (jaundice). The fact that the majority of cases of HBV infection are subclinical contributes to the spread of this virus.

Background

Epidemiology

The incidence of HBV infection is increasing. About 200 million people worldwide are carriers of HBV. In the United States, most new cases of HBV infection occur among young adults. The Centers for Disease Control and Prevention (CDC) estimates that there are 200,000 to 300,000 new cases of HBV a year and that about 1.5 million people in the United States are infected. HBV infection is higher in certain at-risk populations in which 5 to 20 percent of persons are HBsAg positive, than in the general U.S. population. The incidence is highest in drug users, heterosexuals with multiple sexual partners, men who have sex with other men, persons in certain health care occupations, and persons born outside the United States in areas where HBV is endemic. The highest serologic evidence for prior HBV infection is in the following categories:

1. High risk - immigrants from Southeast Asia, China, and Africa; clients in residential institutions for the developmentally disabled; injection drug users; men who have sex with other men; household contacts of HBV carriers; hemodialysis patients; and persons with multiple heterosexual partners
2. Intermediate risk - prisoners (male), staff workers in institutions for the mentally retarded, and health care workers with frequent blood contact

Hepatitis B is spread primarily by the HBV chronic carrier. In the United States, there are an estimated 1 to 1.5 million persons with chronic HBV infection who are potentially infectious to others. Hepatitis B infection may also be spread by persons with the acute disease, since persons with acute hepatitis B may be infectious but asymptomatic.

Course of the Disease

After the initial exposure, the incubation period averages 60 to 90 days, with a range of 6 weeks to 6 months; infected persons may be infectious to others before the onset of symptoms. With acute icteric hepatitis, the onset of symptoms is gradual and includes loss of appetite, vague abdominal discomfort, weight loss, fever, nausea, vomiting, and diarrhea; dark tea-colored urine; and muscle aches and skin rash, which may occur prior to the development of clinical jaundice. In the majority of cases of HBV disease, however, the infection is self-limited, with no evident jaundice. For this reason, most persons do not know that they are infected. Subclinical infection may occur with no symptoms.

Approximately 10 percent of infected persons go on to develop chronic hepatitis, and 25 percent of this group may develop cirrhosis or hepatocellular carcinoma at some time.

Program Issues for Drug Treatment Settings

The prevalence of HBV infection among injection drug users in the United States ranges from 60 to 80 percent, depending on the region. Because of this high prevalence, all persons enrolled in drug treatment programs and all clinical staff should be screened for prior HBV infection. Screening for HBV infection in methadone treatment

programs is required by some States but is not mandated in the Federal regulations. Such screening is considered good medical practice, and should be accompanied by appropriate counseling, vaccination, and needed medical followup. Screening for HBV in these high- risk groups has been shown to be cost-effective.

In setting up a screening and treatment or referral program, the following medical issues and components need to be included:

- Screening and vaccination, if appropriate, need to be a routine part of care in methadone treatment programs. If there is no serologic evidence of prior HBV infection, hepatitis B vaccine should be administered.
- At-risk, previously unexposed persons must be vaccinated; if at-risk persons are not vaccinated, they should be rescreened every 6 to 12 months.
- After a known exposure to HBV, an at-risk person should be given the hepatitis B vaccine as well as hepatitis B immune globulin (HBIG) in a timely fashion.
- Periodic serologic screening for HBV and appropriate followup should be an ongoing concern in methadone treatment programs.
- The risk of occupational exposure to bloodborne pathogens, including HIV and HBV, exists for employees who can be reasonably anticipated to have contact with blood or other potentially infectious material while performing their duties. Any health care worker at such risk must be offered the hepatitis B vaccination unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has shown the employee is immune, or the vaccine is contraindicated for medical reasons. If the employee refuses the hepatitis B vaccination series, the employee must sign an Occupational Safety and Health Administration (OSHA) vaccination declination form.

Special Considerations With Infected Patients

Methadone and other drug treatment programs need to be aware of the following issues with regard to those patients infected with hepatitis B:

- Certain prescribed drugs may be contraindicated for persons with ongoing liver disease secondary to HBV infection. These drugs include methadone, isoniazid (INH), rifampin, oral contraceptives, and antiseizure medications.
- The use of a interferon to treat chronic active hepatitis B infection is a medical issue for those persons who are positive for hepatitis B surface antigen (HBsAg) and show evidence of chronic active hepatitis. For some infected persons, liver transplantation may be the appropriate therapeutic option.
- Persons known to be HBsAg positive should be counseled regarding safer sex practices and notification of partners and household contacts. In addition, they should be advised not to share toothbrushes, drinking cups or glasses, razors, rubber gloves, towels, or drug paraphernalia. However, since HBV is not spread through food or drink, persons who are infected with HBV may handle food for others.
- Those who care for infected infants or children should be counseled about not allowing the children to share their toys, baby bottles, or other such objects.

Other Program Considerations

Clients Who Refuse Testing

Clients who refuse HBV testing should not be excluded from a treatment program because of presumed or actual viral hepatitis. Admission to a drug treatment program should not be restricted unless illness precludes the patient's participation in the program and limits the patient's ability to carry on routine daily activities.

Education and Counseling

Patients in drug treatment programs need to be educated about relevant health issues and sexual practices, since this is a major means of preventing the spread of HBV and other infectious agents. The education should be ongoing and relevant to the issues of each treatment program. For further information, see "Issues for Counselors."

Universal Precautions

Staff should employ universal precautions when coming in contact with body fluids, regardless of the documented status of a person for potentially infectious bloodborne pathogens (including HIV and HBV). All blood and other body fluids containing visible blood should be considered potentially infectious. In addition, universal precautions should be applied to body tissues and to cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid.

General Guidelines

With persons who have acute viral hepatitis, CDC guidelines for contact isolation should be followed. Patients and staff should observe good personal hygiene, especially hand washing. Staff who will be drawing blood should follow the guidelines listed in [table 1](#). When disposing of infectious or potentially infectious waste, local and State regulations should be followed.

Mandatory Reporting Procedures

All States mandate that cases of clinical viral hepatitis be reported. Reporting of chronic carriers (HBsAg positive or hepatitis B core antibody positive with a negative hepatitis B surface antibody and antigen) should be done promptly in accordance with local and State health department regulations to facilitate contact tracing.

Resource Lists for Guidelines and Reporting

All methadone and other drug treatment programs should develop a resource list providing information on local, State, and CDC guidelines for screening and treatment of HBV, as well as for reporting of HBV-infected persons to health departments.

Screening

Indicators for Screening

Methadone and other drug treatment facilities need to screen all patients, as well as at-risk staff members. Any health care worker whose tasks involve contact with blood or blood-contaminated body fluids should be screened. See [table 2](#) for behavioral risk indicators and [table 3](#) for medical indicators of active hepatitis.

Screening Techniques

Screening Tests for Acute Viral Hepatitis B

In screening for acute hepatitis B, the two critical components are (1) the clinical findings and (2) the serological tests. For clinical findings (medical indicators for active hepatitis), see [table 3](#). The serologic tests determine the presence of hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc) immunoglobulin M (IgM) and immunoglobulin G (IgG), and hepatitis B surface antibody (anti-HBs).

When screening for acute HBV infection, it must be remembered that acute HBV may present clinically the same as acute hepatitis A, acute hepatitis C, Epstein-Barr virus (infectious mononucleosis), and cytomegalovirus infection. In addition, hepatitis may be caused by certain drugs, such as isoniazid and phenytoin (Dilantin), as well as by alcohol and industrial chemicals (for example, benzene).

Screening Tests for Prior HBV Infection

In screening for prior infection, the results of serologic tests are helpful in determining if the infection is acute or occurred in the recent or distant past and whether the patient is immune or infectious to others. The initial serologic tests measure hepatitis B surface antigen, hepatitis B core antibody, and hepatitis B surface antibody. All of these tests should be done as the initial screen to avoid the necessity of having the patient return for additional testing, as would be the case if only the IgG core antibody is done as the initial screening test and it turns out to be positive. Liver function tests should be drawn and sent to the laboratory at the same time as the initial screen. The presence of immunoglobulin M antibody to hepatitis B core antigen helps to identify recent infection in most cases. However, in patients with a flareup of chronic HBV infection, serum anti-HBc IgM may be present.

Test results may be interpreted as follows:

If HBsAg positive:

1. Obtain results of the liver function tests that measure aspartate aminotransferase (AST/SGOT) and alanine aminotransferase (ALT/SGPT); if transaminases are elevated, this is consistent with acute or chronic hepatitis B. In addition, however, other causes of hepatitis unrelated to HBV need to be excluded, such as viral hepatitis A, viral hepatitis C, alcoholic hepatitis, or drug-induced hepatitis, all of which may be present in someone who also has hepatitis B.
2. Obtain results of anti-HBc.
 - If anti-HBc IgM is positive, this represents recent, acute infection or a flareup of chronic HBV infection.
 - If anti-HBc IgM is negative but anti-HBc IgG is positive, this represents chronic hepatitis B infection in most people.
 - To identify a person as having chronic HBV infection, the HBsAg must have been positive for 6 months or longer. Therefore, some people may require repeat testing in 6 or more months.
3. If HBsAg is positive, most laboratories will then test that same serum sample for the hepatitis Be antigen (HBeAg), also called the Dane particle, and the hepatitis Be antibody (anti-HBe).
 - If HBeAg and HBsAg are both positive, this represents a high level of potential infectivity to other persons.
 - If HBsAg and anti-HBe are both positive, the patient is less infectious to others than if HBsAg and HBeAg are both positive.
 - Since the approach to counseling, therapy, or diagnosis does not differ for a patient who is highly infectious versus one who is less infectious, there is no need to test for the presence of HBeAg or anti-HBe if these tests are not routinely performed.
4. Do a complete history and physical examination.

If HBsAg negative:

1. Review the results of hepatitis B surface antibody and anti-HBc.
 - If anti-HBs is positive, this represents past infection with HBV. If anti-HBc IgM is positive, this represents a recent infection. If anti-HBc IgM is absent, infection occurred in the distant past regardless of the presence or absence of anti-HBc IgG.
 - The presence of both anti-HBs and anti-HBc - with both negative HBsAg and anti-HBc IgM - represents past infection with HBV and immunity.
 - With recent infection, anti-HBc IgM alone may be present at a high level after the disappearance of HBsAg and before the appearance of anti-HBs.
 - Anti-HBc alone may also represent past infection, and such a person is not infectious to others.
 - Anti-HBs alone is a marker of protective immunity for persons vaccinated against HBV.
2. The correlation of the serologic test results for HBV infection with the stage of disease is shown in [table 4](#). If there are questions about the interpretation of the test results, these should be reviewed with a physician knowledgeable about viral hepatitis.

3. If the test results do not clearly establish the stage of infection, a second blood sample may need to be obtained after 1 or more months.

Medical Management Issues

Medical Management Based on Screening Tests

If the test results do not clearly explain the stage of HBV infection or if there is laboratory and/or clinical evidence of acute or chronic hepatitis of uncertain etiology, the patient should be referred out for further medical evaluation and followup.

Any patient with no serologic evidence of prior exposure, including a negative anti-HBs, should be offered hepatitis B vaccine. Any patient who is a healthy HBsAg carrier or who has chronic hepatitis B should be counseled about risk behavior for exposing other persons.

Medical Prognosis

Recovery usually occurs in 4 to 6 weeks. Fulminant acute hepatitis with liver failure and encephalopathy is rare. Prolonged acute hepatitis with symptoms for more than 3 to 4 months occurs in 3 to 5 percent of cases. Relapsing hepatitis after the initial episode may occur one or more times.

Persistent HBV infection occurs in approximately 10 percent of persons infected with HBV. Persons with persistent HBV infection remain HBsAg positive. Overall, 70 percent have chronic persistent hepatitis and 30 percent have chronic active hepatitis with the following characteristics:

- Chronic persistent hepatitis is usually asymptomatic, with persistent or recurrent elevation in AST and ALT, without jaundice and with mild hepatosplenomegaly.
- Chronic active hepatitis (CAH) is characterized by intermittent or no episodes of jaundice. When jaundice occurs, transaminases (ALT and AST) are markedly elevated. The prognosis is variable, and many persons with CAH develop cirrhosis. Cirrhosis, hepatic failure, and premature death may occur. Persons with CAH should be under appropriate medical supervision.
- The diagnosis of chronic active or chronic persistent hepatitis is based on certain characteristic findings on histopathologic examination of hepatic tissue. To make these diagnoses, therefore, a liver biopsy is necessary.

Persons with chronic hepatitis who remain HBsAg positive for more than 6 months are said to be chronic carriers. Chronic carriers of HBV constitute a human reservoir of persistently infected persons responsible, in large part, for the ongoing spread of HBV.

Clinical Management (In-House or Referral)

Treatment

Treatment of chronic active hepatitis with a interferon may be appropriate and effective. However, such treatment would have to be done with qualified medical supervision.

Vaccination

Cases of HBV infection are associated with the risk group behaviors outlined previously; vaccination programs should be directed at persons with known risk behavior. Injection drug users who are not already infected with HBV should be vaccinated as early as possible after their drug use begins. Vaccination and appropriate, timely post-exposure prophylaxis are of proven efficacy in preventing hepatitis B.

The currently available hepatitis B vaccines are produced by recombinant DNA technology. There is no risk of infection with any viral or other infectious agent. Currently licensed HB vaccines include Recombivax-HB (Merck, Sharpe and Dohme) and Engerix-B (SK Biologicals). For recommended dosages by population group, see [table 5](#).

In addition, these guidelines should be followed in administering vaccine:

1. The vaccine is administered as a series of three intramuscular doses given in the deltoid muscle of adults and children. The second and third injections should be given at 1 and 6 months after the first dose. The Engerix-B vaccine is also licensed to be given in four doses administered at 0, 1, 2, and 12 months.
2. Postvaccination testing for serologic response (anti-HBs) is advised for certain groups: persons with HIV infection and dialysis patients and staff, including both adults and children.

When the series is properly administered, there is a protective antibody response in more than 90 percent of healthy adults and in more than 95 percent of infants, children, and adolescents. Ensuring completion of the 3- to 4-series vaccine may be difficult with injection drug users and others at risk. A study of injection drug users showed that only 81 percent of them had received any HB vaccine. Among those who received any vaccine, 61 percent received only the initial dose, 24 percent received the first two doses, and only 15 percent received all three doses. In this study group, 19 percent received no vaccine; 86 percent of those receiving no vaccine were in correctional institutions or drug treatment centers - sites where recommended doses could have been administered.

The Centers for Disease Control and Prevention recommendations about how to proceed when the vaccination series has been interrupted are listed in [table 6](#).

Post-Exposure Prophylaxis for Hepatitis B

Any percutaneous exposure (needlestick, laceration, or human bite) or permucosal exposure (ocular or mucous membrane) to potentially HBV-infectious blood is of concern. To decide who requires prophylaxis, the following information is needed:

1. Is the source of the blood available?
2. What is the HBsAg status of the source?
3. What is the hepatitis B vaccination status and vaccine response of the exposed person?

[Table 7](#) shows CDC recommendations for prophylaxis of sex partners and household contacts of persons with HBV infection.

Medical Management With Special Groups

With HIV Co-Infection

Persons infected with HIV may have a suboptimal response to HB vaccine even if the vaccine is properly administered. For this reason, consideration should be given to administering the higher dose ([see table 5](#)) of HB vaccine to HIV-infected persons. This higher dose of HB vaccine is currently recommended for dialysis patients and immunocompromised patients; HIV-infected persons may also benefit from this increased dose of HB vaccine.

HIV-infected persons should be tested postvaccination for immunity. The anti-HBs level should be measured 1 to 6 months after completion of the vaccine series. For persons who do not respond to the primary vaccine series, one or more additional vaccine doses may provide protective immunity.

A person is considered to have protective immunity against HBV if that person has a concentration of anti-HBs of at least 10 mIU/mL by radioimmunoassay. There is concern that, over time, the protective immunity may diminish. For an HIV-infected person who did not respond appropriately to the initial vaccine series and was, therefore, given one or more additional vaccine doses, there are currently no CDC recommendations for testing that person to demonstrate protective immunity or for administering additional vaccine.

With Pregnancy and HBV Infection

A woman who has active hepatitis should be advised not to become pregnant. HBsAg-positive women should be evaluated for HBV-related liver disease as described in the screening guidelines.

All pregnant women should be tested for HBsAg early in pregnancy. If the woman is at high risk for HBV infection, the HBsAg test should be repeated late in pregnancy, even if the woman was initially HBsAg negative. High-risk women would include injection drug users, those with other sexually transmitted diseases during the pregnancy, those with multiple sexual partners during the pregnancy, and those with clinically evident hepatitis.

Pregnant women with known risk behavior should be vaccinated, since hepatitis B vaccine may be given safely to pregnant and lactating and/or breastfeeding women. If the pregnant woman is HBsAg positive, the general guidelines apply for screening and vaccinating of her at-risk household contacts as well as her drug and sexual partners.

A pregnant woman not tested for HBsAg prior to the time of delivery should be tested at that time. The risk of perinatal transmission from an HBV-infected mother to her infant ranges from 10 to 85 percent, according to various studies. If the mother is both HBsAg and HBeAg positive, the risk of transmission is greater. See [table 8](#) for CDC guidelines for vaccinating infants.

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Chapter 13 - Viral Hepatitis C

Hepatitis C virus (HCV) was isolated in 1988. In the United States, multiple studies have confirmed that the hepatitis C virus is the viral agent causing non-A, non-B hepatitis. HCV infection is associated with both acute and chronic liver disease.

HCV, like hepatitis B virus, is a bloodborne pathogen. Most transmission occurs by direct contact with infected blood or blood products. Contact with contaminated needles or syringes is also a means of exposure. HCV may be spread by sexual contact, but the risk of infection is less than with exposure to blood. The number of infectious viral organisms is presumably greater in blood than in vaginal secretions, semen, or saliva.

The first serologic test for HCV antibody became available in 1990, allowing a better understanding of the prevalence of HCV. There are several additional tests currently available. The second generation tests currently available are sensitive and specific. These tests are reliable when used in high-prevalence populations, but in low-prevalence populations the positive predictive value is only 50 percent. Among substance abusers, however, especially injection drug users, the prevalence of HCV infection is high; therefore, the second generation tests are reliable. There are additional confirmatory tests available that may be indicated.

Background

Epidemiology

Persons at increased risk for acquiring HCV infection are injection drug users and persons with multiple sexual partners. Injection drug use is the risk factor for acquisition of HCV infection in approximately 35 percent of reported cases. Parenterally transmitted hepatitis attributable to HCV also exists among recipients of transfused blood products, hemodialysis patients, and health care workers. Post-transfusion hepatitis occurs in about 50 to 80 percent of persons exposed to HCV-infected blood. HCV may also be transmitted by close sexual or household contact and may be transmitted from an infected mother to her fetus or neonate. The risk to the infant may be increased when the mother is also HIV infected. In about 40 percent of cases of HCV infection, no identifiable risk factor is found.

Course of the Disease

Approximately 50 to 75 percent of acute HCV infections in adults are asymptomatic. Acute HCV infection may be subclinical or may be clinically manifested by vague abdominal discomfort, anorexia, nausea, vomiting, and jaundice with elevated liver enzymes. Fulminant hepatitis may occur, but rarely.

As many as 60 to 70 percent of persons with acute HCV infection will develop chronic hepatitis. In patients who have acquired HCV infection in the community, approximately 7 to 43 percent have developed chronic hepatitis; about 10 percent of those who developed chronic hepatitis have in turn developed cirrhosis. In persons who have had a transfusion exposure to HCV, approximately 50 percent have developed chronic hepatitis and approximately 10 to 20 percent of those who developed chronic hepatitis in turn have developed cirrhosis. The diagnosis and medical followup of HCV-infected persons will be an ongoing medical concern in the coming years, now that interferon is available to treat severe and progressive cases of chronic active HCV infection and liver transplantation is feasible for some people.

Program Issues for Drug Treatment Settings

The seroprevalence rate of HCV infection in injection drug users ranges from about 50 percent to 90 percent in some areas. Since the rate of HCV infection in drug users is high, the screening for and management of this infection are important issues for methadone and other drug treatment programs. In drug treatment programs, hepatitis C testing should be requested when a patient's liver function profiles are elevated and all other possible causes of the inflammation have been ruled out. Both the treatment of symptoms and palliative support are indicated.

Methadone maintenance programs need to be aware that methadone dosing may be hazardous in persons who have severely compromised liver function resulting from viral hepatitis of any type. Any patient who is suspected of having acute or chronic viral hepatitis should be evaluated for continuation of and/or adjustments to pharmacological therapy.

Laboratory and Other Testing

Methadone and other drug treatment sites that are instituting a screening program for HCV infection should consider the following:

- The laboratory doing the testing needs to be qualified to do HCV serologic testing.
- Even with the improved testing now available for HCV, there are still some problems with false-positive and false-negative results. Because of this, some tests will need to be repeated or interpreted by a knowledgeable physician.
- Direct-care staff who have percutaneous exposure to blood or body fluids from an HCV-infected person may benefit from receiving serum immune globulin, as described under "Medical Management Issues."

Special Considerations With Infected Patients

Patients with serologic evidence of HCV infection should be referred to a physician, preferably a liver specialist. Chronically infected HCV patients should be evaluated medically on a routine periodic basis to monitor the course of their liver disease.

Other Program Considerations

Patients Who Refuse Testing

Patients who refuse screening should be treated as if they are potentially infected with HCV, but they should not be excluded from treatment programs solely on the basis of presumed or actual infection. Admission to a treatment program should not be restricted unless the illness precludes participation in the program and limits the person's ability to perform activities of daily living.

Staff Procedures

All staff members should implement basic infection control measures, including universal precautions (blood and body fluid precautions). Good personal hygiene, especially hand washing, should be observed by both staff members and patients. Disposable units should be used, and syringes, needles, and other equipment used for parenteral injections must be properly sterilized if not disposable.

Education and Counseling

Patients should be advised to minimize intimate contact with persons who may be infected with HCV. Patients should use condoms and follow safer-sex guidelines. Patients should not share personal items such as toothbrushes or razors. Health and sex education are of major value in primary prevention and should be provided whenever possible.

Reporting

Requirements for reporting of acute cases of hepatitis C to local and State health departments vary among States. Check with your State health department. Programs need to coordinate contact tracing and partner notification concerning hepatitis C with local health authorities.

General Guidelines

Isolation is not necessary for patients with HCV infection. However, patients who are hepatitis C antibody positive should be advised not to share razors, toilet articles, toothbrushes, or drinking and eating utensils.

Screening

Indicators for Screening

Screening for hepatitis C virus on a routine basis is controversial because of the lack of documented effective prevention measures, such as a vaccine. In general, drug treatment programs should consider screening patients to identify those infected with HCV.

Certain patients and staff members should be screened. Any person in a treatment program who has an elevated serum alanine aminotransferase (ALT) should be screened for antibody to HCV. Patients should be tested for hepatitis C if their liver enzymes are elevated and all other possible causes of the inflammation have been ruled out. Such causes could include other infectious agents and adverse reactions to medications and

treatment regimens. In addition, any health care worker who sustains a needlestick or other exposure to blood or blood-contaminated body fluids should be screened. See [table 1](#) for behavioral risk indicators.

Clinical/Medical Presentation

Acute Infection

Approximately 50 to 75 percent of acute HCV infections in adults are asymptomatic. When the acute HCV infection is symptomatic, the illness is no different from any other form of viral hepatitis. See [table 2](#) for symptoms.

Chronic Infection

Symptoms of chronic hepatitis are present in up to 60 to 70 percent of persons with chronic, ongoing HCV infection; these symptoms may include fatigue and malaise. With chronic hepatitis from HCV infection, clinical jaundice may or may not be present.

Screening Techniques

Preliminary Evaluation

The preliminary evaluation for acute or chronic HCV infection should include the following elements:

1. Check for presence of symptoms associated with liver disease
2. Take a history and conduct a physical examination
3. Compile a complete review of patient drug use, including illicit, prescription, and nonprescription drugs; toxin exposure; and alcohol consumption. Many different drugs are hepatotoxic either alone or in combination.
4. Perform liver function tests, including the following:
 - Aspartate aminotransferase (AST)
 - Alanine aminotransferase (ALT)

Serologic Screening for Hepatitis C Virus

In 1989, a portion of the genome of a non-A, non-B viral agent was cloned and designated the hepatitis C virus. The entire HCV genome has now been sequenced. Specific assays for HCV have been developed to determine the presence of hepatitis C antibodies. The presence of these antibodies is diagnostic of HCV infection.

In the majority of cases, these assays detect HCV antibodies within 20 weeks of exposure. There are several assays currently available to detect the presence of antibodies to HCV. They include the first generation enzyme immunoassay, which has now been replaced by the more sensitive and specific assays, including the Abbott HCV EIA 2.0, Abbott Laboratories, an enzyme immunoassay; the Ortho HCV ELISA test, Ortho Diagnostics, Inc., an enzyme-linked immunoassay; the supplemental anti-HCV immunoblot system (Matrix HCV, Abbott); and the recombinant immunoblot assay system (RIBA-1, Ortho Diagnostics). In addition, some laboratories are analyzing serum samples for the presence of HCV ribonucleic acid (RNA) after amplification with PCR (polymerase chain reaction).

Each center testing for HCV needs to arrange to send the serum samples to a qualified reference laboratory. If interpretation of the results is not clear, the center should discuss the results with a liver specialist.

Medical Management Issues

Medical Management Based on Screening Tests

If the clinical and serologic evaluation for HCV infection reveals evidence of acute or chronic hepatitis, the client should be referred out for further medical evaluation and followup. Any patient with serologic evidence of hepatitis C infection should also be counseled about the risk of transmission to others. An infected person may transmit infection through continued injection drug use that involves sharing of needles or paraphernalia. HCV infection may also be acquired by sexual exposure to an infected person. However, this route of transmission is less efficient than the bloodborne route of transmission.

Medical Prognosis

Acute Infection

If acute infection is symptomatic, recovery occurs in 4 to 6 weeks. Fulminant HCV infection with acute HCV is rare, but it is associated with 90 percent mortality when it occurs.

Chronic Infection

Chronic HCV infection is associated with chronic active hepatitis, with or without cirrhosis, in about two thirds of chronically infected persons. Over a period of many years, cirrhosis with hepatic failure or hepatocellular carcinoma may develop.

Clinical Management (In-House or Referral)

Treatment

Patients with serologic evidence of HCV infection should be referred to a physician, preferably a liver specialist, who can make appropriate recommendations for followup. Some infected patients may require a liver biopsy, treatment with α -interferon, or possibly even a liver transplant.

Chronically infected HCV patients should be medically evaluated on a routine basis to monitor the course of their liver disease. Treatment with α -interferon is recommended only for those persons with advanced, symptomatic, chronic hepatitis C infection. Treatment with pegylated α -interferon is available only from tertiary-care facilities.

Vaccination

No vaccine is currently available.

Post-Exposure Prophylaxis for Hepatitis C

Post-exposure treatment with immune globulin (Ig) should be considered for any staff member or patient with a percutaneous or mucous membrane exposure to anti-HCV-positive blood or body fluids. There are, however, no good data to suggest that Ig in this setting is effective, and consultation with a physician knowledgeable about this issue should be obtained. If a decision is made to administer Ig, it should be given as soon as possible following the exposure. Ig is given intramuscularly at a dose of 0.06 ml/kg of body weight.

Medical Management With Special Groups

With HIV Co-Infection

As with other patients, hepatitis C testing should be requested when a patient with HIV has elevated liver enzymes and all other possible causes of the inflammation have been ruled out.

With Pregnancy

Hepatitis C testing should be requested when liver enzymes are elevated and all other possible causes of the inflammation have been ruled out. At present, there is no specific intervention recommended for infants born to mothers who are positive for anti-HCV.

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Chapter 14 - Viral Hepatitis A

Hepatitis A virus (HAV) is a ribonucleic acid-containing virus that causes acute viral hepatitis. Infection with hepatitis A virus, unlike infection with viral hepatitis B, C, or D, causes only an acute illness that is usually self-limited. HAV does not lead to either chronic hepatitis or a carrier state.

The disease is spread mainly by the fecal-oral route or by exposure to fecally contaminated food and water. Most persons are infected by contact with a person with hepatitis; male sexual activity involving sex with other men; foreign travel to developing regions or regions with poor sanitation, including Africa, the Middle East, Asia, and Central and South America; contact with infected children attending day care centers; or illicit drug use. Rarely, the disease is transmitted via transfusion of blood products from a donor who gave blood during the viral incubation period.

Person-to-person transmission is responsible for most of the transmission of hepatitis A. Contaminated produce, water, and food (particularly shellfish) continue to cause common-source outbreaks. Transmission of hepatitis A within families is common.

Background

Epidemiology

In the United States, national rates of hepatitis A have tended to fluctuate in cycles, with an increase in the number of reported cases occurring every 10 years. In 1992, over 21,000 cases of viral hepatitis A were reported in the United States by the Centers for Disease Control and Prevention (CDC), but the incidence of infection is estimated to be several times higher. Since 1983, the age-specific rates have not been significantly different.

Outbreaks of hepatitis A among drug users have been recently reported. The Centers for Disease Control and Prevention (CDC) has proposed two possible explanations for this occurrence. One explanation is that HAV is being transmitted by injection or ingestion of contaminated drugs, and the other is that HAV is being spread by person-to-person transmission as a result of sharing needles, sexual contact, or poor sanitary and personal hygiene conditions.

Course of the Disease

In children and young adolescents, about 80 percent of infected people are asymptomatic and have no jaundice. In the adult population, jaundice usually occurs after an incubation period of 15 to 40 days; it may be associated with fever and diarrhea. Hepatitis A is a self-limited illness in most cases. Relapsing hepatitis or cholestatic hepatitis may occur in a small number of cases, but fulminant hepatitis is rare.

Program Issues for Drug Treatment Settings

Drug users are considered a population at high risk for hepatitis A. Several seroepidemiologic studies have shown higher rates of viral hepatitis A antibody among drug users than in the general population; hepatitis A is a marker for injection drug use among young adults.

Screening and Prevention

There is no need to conduct routine serologic screening to establish prior HAV exposure. However, the following screening and prevention procedures should be done:

- Serologic screening is appropriate for persons with jaundice.

- Persons should be screened for HAV infection if they have clinical manifestations of acute hepatitis or intimate contact with a person with known acute HAV infection.
- Post-exposure prophylaxis with immune serum globulin should be given to persons exposed to HAV who have had no prior HAV infection (i.e., are anti-HAV negative).
- Health care workers should be screened for HAV only if they have known intimate contact exposure or symptoms of acute viral hepatitis.

Other Program Considerations

Education and Counseling

Persons enrolled in drug treatment programs should be educated about the way that this and other hepatitis viruses spread. Behaviors that place persons at risk for HAV infection include having unprotected sex, injecting drugs, having multiple injection-drug partners, sharing or using contaminated drug paraphernalia, using commode water as a diluent for drugs, smuggling drugs rectally, and having poor personal hygiene.

Reporting Procedures

Reporting of HAV to local and State health departments is required and should be done in a timely manner to prevent or limit a community outbreak of hepatitis A.

Medical Management Issues

Clinical Manifestations

After exposure to hepatitis A virus, the incubation period prior to the development of clinical manifestations of infection is usually 28 to 30 days. Infected persons are contagious before the development of overt signs and symptoms.

The most common manifestations of infection are fatigue, jaundice, dark urine, and light-colored stools. Other symptoms include loss of appetite, distaste for cigarettes, nausea, vomiting, and abdominal pain; less common symptoms are fever, chills, headache, muscle pain, joint pain, and diarrhea. These clinical manifestations, combined with elevated liver aminotransferases, aspartate aminotransferase (AST), and alanine aminotransferase (ALT), are consistent with viral hepatitis. The definitive diagnosis of acute viral hepatitis A is made by the serologic presence of immunoglobulin M (IgM) anti-HAV (representative of acute infection within the past 6 to 12 months). Past exposure can be diagnosed by the presence of immunoglobulin G (IgG) anti-HAV.

Once a person has been infected with HAV, protective immunity is long lasting.

Medical Prognosis

For most infected persons, the acute illness lasts from 1 to 3 weeks. However, it may take some time for all symptoms to resolve. HAV infection does not cause chronic disease; a year after acute hepatitis, liver enzymes should be normal.

Some infected persons may have cholestatic jaundice or relapsing hepatitis A. Rarely, patients may develop fulminant and even fatal hepatitis.

Clinical Management

Treatment

There is no specific treatment for hepatitis A other than treating its symptoms. In general, patients should reduce their level of activity. Bed rest may be appropriate in the initial stages, but studies have shown that normal activities, and even heavy physical exercise, do not alter the course of the disease during the recovery period. Alcohol should not be consumed during the acute phase.

Some persons may have a prolonged period of jaundice, for up to 12 weeks, complicated by diarrhea, weight loss, and pruritus. Such persons should be under the supervision of a physician knowledgeable about HAV. Persons with fulminant hepatitis A infection require hospitalization and intensive supportive care. Fulminant hepatitis is usually fatal.

Prevention

Persons with no prior HAV infection (i.e., anti-HAV negative) who are known to have been exposed to HAV should be given immune serum globulin (ISG). A dose of 0.02 ml/kg of ISG should be given as soon as possible, but within no more than 2 weeks of the exposure.

Since there is no currently licensed vaccine for HAV, preventing the spread of this virus depends on the maintenance of high standards of hygiene.

Chapter 15 - Viral Hepatitis D

Viral hepatitis D is caused by the hepatitis delta virus (HDV). HDV infection occurs in persons with concurrent hepatitis B virus (HBV) infection who are hepatitis B surface antigen positive. Hepatitis D may occur concurrently with acute HBV infection or as an acute superinfection in a person with chronic HBV infection. Delta virus is a defective RNA virus that requires the helper function of HBV for replication.

Percutaneous spread among parenteral drug users is not unusual. HDV may also be transmitted via transfusion and from person to person among intimate or household contacts. The rate of infection is high in hepatitis B surface antigen (HBsAg)-positive prostitutes and in homosexual or bisexual men, as well as among parenteral drug users. About 5 percent of homosexual men are infected.

Background

Epidemiology

HDV infection is endemic in the general population in certain areas of the world, including parts of South America, Central Africa, southern Italy, and Middle Eastern countries. It is uncommon in China and Southeast Asia - areas where hepatitis B is common, except in high-risk groups, such as injection drug users.

In the United States and most of Western Europe, delta hepatitis is most prevalent among parenteral drug users and hemophiliacs. Epidemics of HDV infection have been reported in some communities of parenteral drug users.

Course of the Disease

The onset of symptoms of hepatitis D - similar to those of hepatitis B - is usually abrupt. As in other forms of hepatitis, jaundice usually develops after the disappearance of symptoms reflecting the initial acute infection. When a person is infected concurrently with hepatitis B and D, fulminant hepatitis is much more likely to occur than with infection with only hepatitis B, and some persons with fulminant hepatitis will die. In addition, patients with hepatitis D superinfection are more likely to progress to chronic liver disease than those patients with HBV infection alone.

Program Issues for Drug Treatment Settings

Viral hepatitis D is of concern to drug treatment programs because of its association with hepatitis B, which affects up to 80 percent of injection drug users in some areas. The prevalence of HDV is estimated to be 20 to 53 percent among drug users who are HBsAg positive. HDV is clinically important because persons co-infected with hepatitis B and HDV are at increased risk of developing more severe liver disease. Hepatitis B vaccination will effectively prevent delta hepatitis. It is mandatory that persons infected with HBV who are HBsAg positive alter their risk-associated behavior to avoid infecting persons not previously exposed to hepatitis B with hepatitis B alone or with both hepatitis B and D if co-infection is present.

Screening and Prevention

Drug treatment programs should screen all patients for immunity to hepatitis B. Routine screening for hepatitis D is not indicated in persons who are HBsAg positive but asymptomatic. However, the following screening and prevention procedures may be appropriate:

- Patients known to be HBsAg positive who have acute or chronic hepatitis may be tested for hepatitis D. The followup care and counseling, however, of a person co-infected with hepatitis D is not different from that of a person who is HBsAg positive. Therefore, knowing if the patient is co-infected with hepatitis D is of limited clinical significance.
- Patients with acute hepatitis B who are not yet HBsAg positive, but are immunoglobulin M (IgM) hepatitis B core antibody (anti-HBc) positive, may be tested for HDV; however, again, the presence of HDV antibody will not alter the care or counseling of such a patient.
- Patients who are HBsAg positive and/or HDV antibody positive should be advised not to share razors, toilet articles, or drinking and eating utensils.
- Patients who are not already immune to hepatitis B virus should be vaccinated against the virus.
- Screening is not necessary in the general population at no risk for HBV or HDV.

Other Program Considerations

Clients Who Refuse Testing

Patients in drug treatment programs who refuse to be screened for hepatitis B and hepatitis D should be treated as potential risks for spreading these infections. However, they should not be excluded from treatment programs on the basis of real or suspected infection.

Universal Precautions

Special care should be taken in clinical settings to avoid accidental sticks with needles, syringes, and other sharp instruments and to follow proper sterilization or disposal procedures. Universal precautions apply for drawing blood or other medically related procedures.

General Guidelines

Persons with hepatitis B and/or D do not need to be restricted or isolated.

Medical Management Issues

Clinical Manifestations

When hepatitis D infection occurs concurrently with hepatitis B infection, the incubation period of between 6 weeks and 6 months is the same for both. When viral hepatitis D infection occurs as a superinfection in someone already infected with hepatitis B, who remains HBsAg positive, the incubation period is thought to be between 2 and 10 weeks, on the basis of experimental infections in chimpanzees. Hepatitis D is most contagious just before the onset of symptoms but may remain infectious indefinitely in the HBsAg-positive person.

Symptoms of hepatitis D are similar to those of hepatitis B. They include fever, malaise, abdominal pain, loss of appetite, pruritus, myalgias, arthralgias, and joint pain. The onset of symptoms is usually abrupt, and jaundice usually develops after the symptoms have disappeared.

The diagnosis of viral delta hepatitis is made by detecting both HBsAg and antibody to delta hepatitis (anti-HDV). In persons with acute HBV infection who have no detectable HBsAg, IgM anti-HBc with anti-HDV is diagnostic of acute co-infection. A liver biopsy is rarely indicated. Persons known to be HBsAg positive with acute or chronic hepatitis may be screened for HDV antibody, although the presence of HDV antibody does not alter the followup of such patients.

Medical Prognosis

Exposure to hepatitis D may worsen the symptoms of hepatitis B. Patients with co-infection are more likely to have fulminant hepatitis than those patients with HBV infection alone.

When acute infection with HDV occurs in the face of an existing chronic HBV infection, especially in persons with progressive, symptomatic chronic disease, there is increased progression of hepatic cirrhosis and hepatic failure. Both co-infection of hepatitis D and hepatitis B, as well as superinfection of hepatitis D, have been associated with fulminant hepatitis. Hepatitis D results in death in between 2 and 20 percent of patients with acute icteric hepatitis.

Clinical Management

Treatment

There is no specific available treatment. For persons with severe hepatitis, only supportive care is given. The treatment of chronic active hepatitis B and coexistent hepatitis D infection with α -interferon would be done only after consultation and referral to a gastroenterologist.

Prevention

Protection against hepatitis D among drug users can be accomplished by vaccinating against hepatitis B. Since HDV infection requires that the person be co-infected with HBV, vaccinating against hepatitis B also confers immunity to hepatitis D. Some 3 to 4 percent of healthy recipients have no response to the hepatitis B vaccine.

Medical Management With Special Groups

With HIV Co-Infection

HIV-infected persons may not develop protective immunity after receiving hepatitis B vaccine. They therefore remain at risk for infection with HBV and HDV.

With Pregnancy

Pregnant women should be screened for hepatitis B infection. If the woman is at risk for HBV infection, she should be vaccinated. The current recommendations of the American College of Pediatrics and the Centers for Disease Control and Prevention are that all infants be immunized against hepatitis B.

Chapter 16 - Gonorrhea

Gonorrhea is caused by the bacteria *Neisseria gonorrhoeae* and results in a broad range of clinical syndromes. Most gonococcal infections are transmitted during sexual intercourse with an infected person. Infants born to mothers with untreated gonorrhea are also at high risk for infection.

Background

Epidemiology

Gonorrhea is the most common bacterial infection reportable to the Centers for Disease Control and Prevention (CDC). There were about 1 million reported cases of gonorrhea in 1978; the number of total cases has declined to about 620,000 cases in 1991. However, the rate of infection in high-risk adolescents has remained unchanged despite the overall decline. Young women between the ages of 15 to 19 years have proportionately the highest rate of infection.

In general, persons at highest risk of being infected with gonorrhea are those with multiple sexual partners; those who exchange sex for drugs, money, or shelter; individuals engaging in sexual activity associated with illicit drug use; and persons engaging in unsafe sexual practices. These same persons are also at risk for human immunodeficiency virus (HIV) infection and other sexually transmitted diseases.

Course of the Disease

The incubation period for gonorrhea in men is usually 2 to 5 days. Concurrent infection with both gonorrhea and chlamydia is common. Without testing, the two infections are difficult to distinguish in patients.

Serious complications of unrecognized gonococcal infection in women include pelvic inflammatory disease (PID) with subsequent infertility or ectopic pregnancy. Men may develop epididymitis. Disseminated gonococcal infection may occur in either men or women.

Program Issues for Drug Treatment Settings

Testing

Testing for gonorrhea is recommended for those patients with indications of infection or for those who have had sexual contact with infected individuals. All persons with gonorrhea should be treated for presumptive

chlamydia, have serologic screening for syphilis, and be offered confidential counseling and testing for HIV infection.

Education and Counseling

Patients should be counseled to refrain from sexual contact until treatment is completed and to refer their recent sex partners (less than 30 days) for examination and treatment. In addition, safer sex guidelines should be followed and condoms used during sexual intercourse to prevent future infections.

Reporting

Reporting to health authorities is required by all States.

Testing and Diagnosis

Diagnostic Techniques

A swab of any infected or potentially infected site, including the male urethra, or urethral exudate if present, or the female endocervix should be Gram-stained and inoculated quickly onto selective media. If appropriate, rectal and oropharyngeal swabs should also be obtained. A Gram stain that shows Gram-negative diplococci within the polymorphonuclear leukocytes is considered diagnostic of gonorrhea.

Gonorrhea and chlamydia often occur together and patients infected with gonorrhea and their sex partners should also be treated for chlamydia. In addition, patients should have a blood test for syphilis and be offered confidential counseling and testing for HIV.

Clinical/Medical Presentations

Gonorrhea causes a broad range of clinical syndromes including a urethral discharge and dysuria in men and a vaginal discharge, dysuria, and pelvic pain in women. Although many persons have these symptoms, a significant number of infected men and the majority of infected women are asymptomatic or have other manifestations of gonorrhea.

More than half of the men infected with gonorrhea may be asymptomatic. Acute urethritis, with urethral discharge and pain on urination, is the most common symptom and occurs after an incubation period of 2 to 5 days. The discharge is usually copious and purulent. Anorectal infection is not uncommon in men who have sex with other men and may be asymptomatic or cause acute proctitis.

Women infected with gonorrhea may be acutely symptomatic, have minor symptoms, or remain asymptomatic. Common symptoms are vaginal discharge, dysuria, and intermenstrual or heavy menstrual bleeding. Finding cervical, uterine, or adnexal tenderness on pelvic examination reflects ascending infection and PID, including possible salpingitis or tubo-ovarian abscess.

Gonorrhea may cause extragenital infection, including exudative pharyngitis and cervical lymphadenitis, and is usually spread by orogenital sexual exposure. The eyes may be infected through contact with genital secretions. A severe conjunctivitis with corneal ulceration may occur.

Gonorrhea may cause perihepatitis by local extension from the fallopian tube in women or bacteremia in either sex with an associated monoarticular or polyarticular arthritis and dermatitis with characteristic pustular lesions. Endocarditis and meningitis are rare complications of disseminated infection.

Medical Management

Prompt detection and treatment of gonorrhea in its early stages are medically important to avoid complications and continued transmission. The recommended treatment regimen for uncomplicated cases is presented in [table 1](#).

Sexual partners of infected individuals should be tested and treated (without waiting for test results) to prevent the spread of the disease if their contact with the infected persons was within 30 days. If testing is not feasible, the sexual partners should be treated presumptively.

Women with possible gonococcal or nongonococcal pelvic inflammatory disease must be evaluated by an expert qualified to assess the appropriateness of outpatient oral versus inpatient intravenous treatment. Women with inadequate or delayed treatment of PID are at significant risk of being infertile.

The patient with possible disseminated gonococcal infection or ophthalmic involvement should be referred to a physician expert in the care of such patients.

Antibiotic-Resistant Strains of Gonorrhea

The treatment of gonococcal infections in the United States has changed because of the spread of antibiotic-resistant strains of *N. gonorrhoeae* (NG) including penicillinase-producing, tetracycline-resistant, and other strains with chromosomally mediated resistance to multiple antibiotics. In addition, the difficulty of correctly diagnosing concomitant infection with chlamydia has modified the recommendations for treatment of gonorrhea.

Medical Management With Special Groups

With Pregnancy

Gonorrhea in pregnancy may cause spontaneous abortion, premature labor, early rupture of fetal membranes, and increased neonatal morbidity. A pregnant woman infected with gonorrhea risks infecting her infant during delivery. Therefore, all pregnant women should have an endocervical culture for gonorrhea during their first trimester and again late in the third trimester.

The recommended treatment regimen for the pregnant woman with uncomplicated gonorrhea is presented in [table 2](#).

Infants born to infected mothers who have been properly treated rarely become infected. If the mother is not treated, the infection may cause conjunctivitis in infants. In a few cases, a more serious, systemic infection of the infant may occur.

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Chapter 17 - Chlamydia

Chlamydia is a bacterial infection caused by *Chlamydia trachomatis*. The disease is transmitted mainly through sexual intercourse with an infected person. Infected mothers may transmit the infection to their newborns. As many as 60 percent of the infants born to women with chlamydia become infected. Chlamydia has a high prevalence, is easily transmitted, is associated with gonorrhea, and frequently lacks overt symptoms. Drug users are at high risk for infection with chlamydia as well as all other sexually transmitted diseases.

Background

Epidemiology

Chlamydia is one of the most common of the sexually transmitted diseases in the United States, with an estimated 4 million new cases occurring annually, according to the Centers for Disease Control and Prevention (CDC). Exact figures on the incidence of chlamydia are not available, since not all States require reporting of the disease to local or State health departments.

The rate of infection for chlamydia, as for all sexually transmitted diseases, is highest in adolescents, young adults, and among drug users. The prevalence of chlamydia among adolescent girls in drug treatment units has exceeded 10 percent in most studies. The prevalence has exceeded 5 percent in studies of adolescent boys.

Course of the Disease

The symptoms of chlamydia, if they occur, usually appear within 1 to 3 weeks after infection. If promptly and properly treated, chlamydia infection is not serious and causes no lasting damage. If it is inadequately treated, however, it can cause potentially serious complications.

Women may develop pelvic inflammatory disease (PID), an infection of the reproductive organs that is usually accompanied by pain in the lower abdomen and fever. Up to one half of PID cases result from chlamydial infection. Gonorrhea is the other leading cause of PID in women. PID also causes an estimated 100,000 women a year to become infertile.

An even more serious potential complication of PID is ectopic pregnancy, which occurs when an egg is fertilized in the fallopian tube. The growing embryo may cause the tube to rupture. Because of the resulting internal bleeding, a ruptured ectopic pregnancy is a life-threatening emergency to the woman.

Program Issues for Drug Treatment Settings

Screening

Screening for chlamydial infection is strongly encouraged, particularly for high-risk pregnant women, adolescents, and patients with multiple sexual partners. Testing for chlamydia infection should be routinely included for adolescent girls and women of childbearing potential having pelvic examinations. Asymptomatic infection may cause mild or silent salpingitis, leading to infertility if untreated.

Education and Counseling

Patients should be counseled to refrain from sexual intercourse until treatment is completed. In addition, safer sex guidelines should be followed and condoms used during sexual intercourse to prevent reinfection.

Reporting

Reporting requirements for cases of chlamydia to local health authorities vary among States. Individual State guidelines should be followed.

Screening

Clinical/Medical Presentations

The early symptoms of chlamydia are often mild or nonexistent, especially in women. Because of this, chlamydia is easily spread among sexual partners. When symptoms do appear, women may experience abdominal pain and dysuria (painful urination) and have a vaginal discharge.

Men infected with chlamydia can develop nongonococcal urethritis (NGU), an inflammation of the urinary tract that is characterized by a mucopurulent penile discharge and sometimes by pain during urination. Chlamydia causes approximately 40 percent of the cases of NGU.

Chlamydia also can cause epididymitis, an inflammation of the epididymis, a part of the male reproductive system in the testicles. Rectal infection in women and men who have sex with men is not uncommon and may cause proctitis. The rectal area is infected through either anal sex or by spread of the infection from the genital area.

Less commonly, the disease also leads to a disturbance in the body's immune system, resulting in chronic arthritis. Chlamydia may also cause acute conjunctivitis in adults.

The symptoms of chlamydia are similar to those of gonorrhea, and the diseases often occur simultaneously. Concurrent infection with both gonorrhea and chlamydia is twice as common in women as in men. Chlamydia infection is found in 35 to 45 percent of women with gonorrhea. Without testing, the two infections are difficult to distinguish in patients. Accurate initial testing and followup after treatment are essential.

Screening Techniques

Isolation of chlamydia in cell cultures of adequate urethral or cervical swabs is the preferred method of detection when feasible.

Nonculture methods include a direct microimmunofluorescent antibody, enzyme immunoassay, and nucleic acid probe tests. The tests are done using urethral or cervical (for women) swab specimens which must contain cells. These tests may be done on men with urethritis or proctitis and on women with acute mucopurulent cervicitis or salpingitis.

Medical Management

Patients with positive test results for chlamydia should be treated with an appropriate antibiotic regimen. All persons with gonorrhea, as well as their sexual partners, should be treated presumptively for probable co-infection with chlamydia.

When the prescribed treatment is completed, routine followup cultures are not needed. If the treatment is not properly completed, persons may be retested. Regardless of the followup test results, the person will require a new, complete course of appropriate antibiotic therapy, and for that reason rescreening may be unnecessary.

A new, single-dose therapy for the treatment of uncomplicated genital chlamydial infection was reported by researchers in September 1992 ([Martin et al. 1992](#)). A single dose of azithromycin, the prototype of a new group of antibiotics known as azalides, proved to be effective in the treatment of chlamydia in 96 percent of

cases studied. The cost of the single dose treatment is significantly higher than the cost of the 7-day treatment regimen, but compliance is less of an issue.

The recommended treatment regimens for uncomplicated urethral, endocervical, or rectal chlamydia infections in nonpregnant patients are provided in [table 1](#).

In order to prevent the spread of the disease, sex partners of symptomatic patients should be evaluated and treated for chlamydia if their last sexual contact with the index patient was within 30 days of onset of the index patient's symptoms. If the index patient is asymptomatic, sex partners whose last sexual contact with the index patient was within 60 days of diagnosis should be evaluated and treated.

Medical Management With Special Groups

With Pregnancy

Chlamydia can be passed from an infected mother to an infant during delivery and may lead to conjunctivitis or pneumonia in the newborn infant. For this reason, routine testing of all pregnant women for chlamydia is recommended.

Appropriate screening should be done at the first prenatal visit and during the third trimester. Women with untreated chlamydia at delivery may develop postpartum endometritis after vaginal delivery and require treatment.

The treatment of chlamydia in pregnancy is presented in [table 2](#).

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Chapter 18 - Herpes Simplex

Genital or rectal herpes is an acute inflammatory infection caused by the herpes simplex virus. Most infections are caused by herpes simplex virus type 2 (HSV-2), but some cases are caused by herpes simplex virus type 1

(HSV-1). Symptomatic cases may represent either primary infection with HSV or recurrent disease, since the herpes viruses have the ability to remain latent in the involved nerve root between outbreaks, and when activated cause recurrent infections.

HSV-2 is usually sexually transmitted by genital-genital or oral-genital contact. Transmission of the virus occurs when the genital or oral mucosa of the uninfected person comes in contact with virus shed by an actively infected person. The infected person may have a symptomatic infection, or more commonly, asymptomatic genital or oral shedding of the virus.

Background

Epidemiology

The occurrence of herpes simplex virus is widespread. The Centers for Disease Control and Prevention (CDC) estimates that 31 million people in the United States are infected with HSV-2 and that there are 200,000 to 500,000 new cases a year. Incidence of the infection is highest in sexually active persons.

Course of the Disease

The incubation period for herpes is from 2 to 7 days; in most cases, the incubation period is closer to 7 days. Persons with primary herpetic lesions are infectious for about 7 to 12 days. Genital, rectal, or oral herpes recurs in 60 to 80 percent of persons whose primary infection was symptomatic. These recurrent episodes of herpes are milder and of shorter duration than the initial outbreak. Treatment of acute outbreaks or suppressive therapy with acyclovir will decrease the symptoms of herpes or the frequency of outbreaks, but will not cure the infection.

Program Issues for Drug Treatment Settings

Testing

Testing for herpes is recommended for patients with genital, rectal, or oral ulcers.

Education and Counseling

Patients should be counseled to abstain from sexual activity while lesions are present. In addition, condoms should be used during sexual contact since asymptomatic shedding may transmit the virus.

The risk of neonatal infection should be explained to all patients - male and female - with genital herpes. Women of childbearing age should be advised to inform their physician of any history of infection if they become pregnant.

Reporting

Reporting to health authorities is not required.

Screening

Clinical/Medical Presentation

Primary herpes infection may be asymptomatic or symptomatic. In women, the primary infection is usually more severe than in men. Any area of the female genitalia may be involved. Herpes simplex infection causes

characteristic blister-like vesicular lesions that quickly rupture and leave shallow, exquisitely tender ulcers with a gray discharge and red base. New lesions may continue to develop for about 1 week.

In men, the primary infection usually involves the penis with the same vesicular lesions.

Both men and women may have dysuria and inguinal lymphadenopathy, as well as flu-like symptoms including fever, headache, malaise, and muscle aches during the first few weeks of infection.

Herpes can also involve the perirectal area or the oral cavity.

Testing Techniques

The diagnosis of herpes may be made by examination of the characteristic lesions. The simplest technique for diagnosing herpes is the examination of cells scraped from the base of an ulcer or vesicle using the Tzanck smear or, for cervical or vaginal lesions, the Papanicolaou (Pap) smear or Tzanck smear.

Other diagnostic tests include an enzyme-linked immunoabsorbent assay (EIA), direct fluorescent antigen (DFA), or viral cell culture.

Medical Management

The recommended treatment for herpes infection is acyclovir. Treatment with acyclovir hastens healing and decreases viral shedding, but does not eradicate the virus. [Table 1](#) presents recommended treatment regimens.

Persons with herpetic lesions should be instructed to keep the area clean and dry in order to prevent secondary bacterial infections. They should also avoid touching the lesions and, if they do touch them, should wash their hands.

Persons with known prior genital or rectal herpes should avoid sexual contact when they have active lesions or have the prodrome of pain, tenderness, burning, tingling, or itching prior to the appearance of active lesions.

Since asymptomatic shedding of infectious virus may occur, persons with known herpes should always use a condom and inform their sexual partner(s).

Medical Management With Special Groups

With HIV Co-Infection

For HIV-infected and other immunocompromised persons, the herpes infection may be more severe and less responsive to therapy. Some persons may require higher and longer doses of acyclovir. Cases of acyclovir-resistant herpes infections are now reported primarily in HIV-infected or other immunocompromised persons. Treatment of severe cases of acyclovir-resistant herpes requires hospitalization and treatment with intravenous foscarnet.

With Pregnancy

Most neonates who are infected with herpes simplex virus at the time of passage through the birth canal are born to mothers with no history of clinically apparent genital herpes. As a result, routine viral cultures during pregnancy to detect viral shedding are not appropriate.

At the onset of labor, all women should be carefully examined for the presence of active lesions. If the woman has signs or symptoms suggestive of active genital herpes, the baby should be delivered by caesarean section.

Infants exposed to herpes simplex virus at the time of delivery may develop disseminated infection with disease involving the skin, eyes, and mouth, or herpes simplex encephalitis. Peripartum or congenital (intrauterine) infection may result in the death of the infant or lead to serious neurologic or ophthalmic complications.

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Chapter 19 - Chancroid

Chancroid is a bacterial infection caused by the *Haemophilus ducreyi* bacillus. This infectious organism is transmitted sexually and penetrates through breaks in the exposed epithelium of the genital mucosa or skin. In most infected people, chancroid presents a painful genital ulcer with inguinal lymphadenopathy. The differential diagnosis for a person with genital ulcers with inguinal lymph nodes includes not only chancroid but also syphilis, genital herpes, and lymphogranuloma venereum. Genital ulcers may serve as a portal of entry for HIV and increase the likelihood of HIV infection after sexual contact with an HIV-infected person. For an HIV-infected person with a genital ulcer, the presence of the ulcer increases the probability of transmission of HIV to an uninfected sex partner.

Background

Epidemiology

The number of cases of chancroid in the United States has increased in recent years, with over 5,000 cases reported in 1987. Due to the difficulty in making a definitive laboratory diagnosis, the disease is underreported.

Information on the transmission and epidemiology of chancroid has come primarily from Africa. Chancroid is most prevalent in subtropical and tropical regions of the world. In such areas, its incidence may be greater than that of syphilis, and close to the incidence of gonorrhea in men. However, chancroid is becoming increasingly common in temperate areas. Individuals from temperate areas who have traveled to tropical or subtropical areas, or who have had sexual contact with people from these areas, are at increased risk for contracting chancroid.

In general, chancroid is usually seen among persons with multiple sexual partners. In the United States, chancroid occurs most commonly in heterosexual men.

Course of the Disease

The incubation period for chancroid is usually from 3 to 5 days, although it may extend up to 2 weeks. Chancroid infection can be transmitted as long as the original sore or oozing lymph node remains infected with the bacteria. Chancroid ulcers typically improve within 3 to 7 days after institution of therapy and healing is usually complete in 2 weeks.

Program Issues for Drug Treatment Settings

Testing

Testing for chancroid is recommended for patients with genital lesions.

Education and Counseling

Patients should be counseled to refrain from sexual contact until treatment is completed. In addition, safer sex guidelines should be followed and condoms used during sexual intercourse to prevent future infection. Patients should be counseled that chancroid has been associated with an increased risk of acquiring HIV infection.

Reporting

Most States require that cases of culture-confirmed or clinically suspected chancroid be reported to local health authorities.

Screening

Clinical/Medical Presentations

In both sexes, chancroid is characterized by one or a few painful, infected sores at the site of the infection. Both men and women rarely have lesions outside the genital area. In men, the lesions occur most often on the penis, where they are visible and generally easily recognized by a trained health professional. Uncircumcised men are at greater risk for infection than circumcised men. In women, the lesions occur primarily in the following areas: fourchette, labia, perianal area, and medial aspects of the thigh. Cervical ulcers and ulcers of the vaginal wall are uncommon.

The chancroid ulcer is painful and bleeds readily. The chancre of primary syphilis is painless. The exudate that oozes from the ulcer is grayish, necrotic, and purulent. In addition, an infected person may have not only the genital ulcer, but also inguinal lymphadenopathy (40 percent of cases). The lymphadenitis is painful and may form an abscess. It is sometimes necessary to aspirate the infected inguinal nodes to prevent rupture and to afford symptomatic relief.

Screening Techniques

There is no serologic test for chancroid. The organism is frequently difficult to recover from the ulcer. The base of the purulent ulcer should be swabbed without cleaning the affected area. The culture specimen should be quickly transported to the microbiology laboratory and inoculated onto appropriate media. The person in the clinic setting who obtains the culture should contact the microbiology laboratory where the specimen is being sent and have the laboratory set up the appropriate media for chancroid. Despite the frequently significant inguinal lymphadenitis, recovery of the organism from the aspirated lymph node is uncommon.

Given the problems with making a specific laboratory diagnosis, the Centers for Disease Control and Prevention (CDC) has defined probable chancroid. A probable case of chancroid is an illness with one or more painful genital ulcers and inguinal adenopathy, a clinical appearance not typical of genital herpes, and negative tests for syphilis (darkfield microscopy and/or serology).

Medical Management

Chancroid responds to treatment with appropriate antibiotics. The recommended treatment regimens are presented in [table 1](#).

The response of chancroid to drug therapy varies among individuals. HIV-infected persons may respond more slowly or require longer therapy and individuals known to be HIV-infected are probably best treated with regimens other than ceftriaxone or azithromycin. The inguinal lymphadenopathy in any infected person may be slow to resolve. Patients should be observed until the genital ulcer has resolved. Serologic tests for syphilis should be done at the time of presentation and again within 3 months of therapy. Herpes simplex culture may be indicated.

Sexual partners who had contact with the infected person within 10 days of the onset of symptoms should be notified and treated whether or not they are symptomatic.

Medical Management With Special Groups

With HIV Co-Infection

From studies done in Africa, it appears that the genital ulcers of chancroid serve as a portal of entry for HIV infection in both men and women. Many persons newly diagnosed with HIV report recent genital ulcers. In addition, persons with HIV infection have more severe and numerous ulcers when infected with chancroid. Chancroid and HIV together amplify the infectivity of each. Controlling the spread of chancroid will serve also to limit the spread of HIV. Any person with chancroid should be tested for HIV infection.

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Appendix D - Resource List

Issues for Treatment Program Administration" this volume, identifies several published guidelines and advisories for infectious disease prevention and control. In addition to the listed guidelines, Federal and State agencies offer a wide variety of related resources; some of them are listed below.

The HIV and Substance Abuse Training Curriculum: A Catalog of Training Material Available from the National Institute on Drug Abuse (NIDA). Federal program contact: Susan L. David, Chief, Community and Professional Education Branch, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10A-39, Rockville, MD 20857. (301) 443-1124, FAX (301) 443-7397.

Directory of Projects: Faculty Development Program in Alcohol and Other Drug Abuse. Published by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the Center for Substance Abuse Prevention (CSAP). Federal program contacts: Lucille C. Perez, M.D., Associate Director for Medical and Clinical Affairs, Center for Substance Abuse Prevention, 5600 Fishers Lane, Rockwall II, Rockville, MD 20857. (301) 443-9351; Frances Cotter, M.P.H., Public Health Adviser, NIAAA, 5600 Fishers Lane, Room 14C-20, Rockville, MD, 20857. (301) 443-1207; and Dorynne Czechowicz, M.D., Associate Director for Medical and Professional Affairs, NIAAA, 5600 Fishers Lane, Room 10A-12, Rockville, MD, 20857. (301) 443-4877.

National Clearinghouse for Alcohol and Drug Information (NCADI) Publications Catalog, Post Office Box 2345, Rockville, MD 20847-2345. 1-800-729-6686 or (301) 468-2600.

The Office for Substance Abuse Prevention (OSAP) National Training System. Federal program contact: Steven Seitz, Project Officer, Training and Evaluation Branch, Division of Community Prevention and Training, OSAP, 5600 Fishers Lane, Rockwall II, Rockville, MD 20857. (301) 443-5276.

The OSAP Prevention Training Information System. Federal program contact: Edward Briggs, (301) 588-5484.

The Federal alcohol and drug clearinghouses listed below can all be reached through one telephone number: 1-800-788-2800. Callers can reach the individual clearinghouses directly at the numbers listed below.

National Clearinghouse for Alcohol and Drug Information (NCADI). 1-800-729-6686. Operated by the Center for Substance Abuse Prevention of the Department of Health and Human Services, NCADI distributes a wide range of printed and audiovisual materials, including posters, fact sheets, curriculum descriptions, and articles. There is a large full-service library. NCADI coordinates the Regional Alcohol and Drug Awareness Network (RADAR), which facilitates access to State and local sources of information about alcohol and other drugs.

National AIDS Clearinghouse. 1-800-458-5231; TTY: 1-800-243-7012. Operated by the Centers for Disease Control and Prevention. Central source of information on AIDS and HIV, including information on the relationship between drug abuse and AIDS. English- and Spanish-speaking reference specialists assist in providing access to more than 6,000 educational materials and computerized databases of materials, service organizations, funding sources, and conferences. Information on AIDS clinical trials is available at 1-800-874-2572.

Drug Information and Strategy Clearinghouse. 1-800-245-2691 and (301) 251-5154. Operated by the Office for Drug-Free Neighborhoods, Department of Housing and Urban Development. Provides information on preventing drug abuse and drug trafficking in public and assisted housing.

Drug Abuse Information and Treatment Referral Line. 1-800-662-4357; Spanish: 1-800-662-9832. Operated by the National Institute on Drug Abuse and the Center for Substance Abuse Treatment. Provides information about drug use, treatment, support groups, and services. Information counselors can discuss problems and provide referrals to State and local drug treatment facilities and programs.

Drug-Free Workplace Helpline. 1-800-843-4971. Operated by the Center for Substance Abuse Prevention. Provides telephone consultation, resource referrals, networking services, and publications to business, industry, and unions to assist in planning, developing, and implementing comprehensive drug-free workplace programs.

There are other sources of information that may be of interest:

Resource Center on Substance Abuse Prevention and Disability. 1-202-783-2900; TDD: (202) 737-0725. Funded by the Center for Substance Abuse Prevention. Answers questions about alcohol and other drug abuse prevention and treatment issues for persons with disabilities; services include customized database searches and fact sheets.

Anti-Drug Information Center. 1-800-225-3784; by modem: 1-800-225-3804. Operated by the Department of Transportation. Provides access to all regulatory information related to the Department's anti-drug programs.

Appendix E - Program Models and Sample Budgets

This section presents three program models and related sample budgets to assist State agency and local alcohol and other drug treatment staff to screen for infectious diseases. The program models reflect the recommendations of alcohol, drug abuse, and mental health (ADM) experts for specific services and staffing. The sample budgets present costing data and assumptions developed by ADM financial experts.

The three program models are

- Model A, which offers counseling and testing for HIV/AIDS ([tables 1](#) and [1a](#))
- Model B, which offers screening for infectious diseases not including HIV/AIDS ([tables 2](#) and [2a](#))
- Model C, which offers a combination of the above two models--HIV/AIDS counseling and testing combined with other infectious disease screening ([tables 3](#) and [3a](#))

These program models have been designed with the understanding that not all States or localities are able to begin new programs or to expand their already-existing screening services. It is further recognized that some States and localities may not offer infectious disease screening and do not expect to receive funds to do so in the future. The program models are intended to be used as guides or standards by those who can develop new services or incorporate some of the guidelines into existing programs.

The accompanying tables present the major tasks, necessary staff, and time estimates for implementing each of the program models. A list of Medicaid reimbursement rates for various medical procedures is included as a guide ([table 4](#)). These rates represent the average reimbursement rate paid to States for specific procedures. A program's actual reimbursement rate for individual procedures may vary.

The sample budgets that follow the tables are based on the program models and lay out the requirements and formulas for estimating program costs. The cost assumptions should be adjusted to conditions that prevail in different geographic areas. For example, to estimate labor costs in a specific location, the prevailing salary/wage rates can be substituted for the rates used here.

Overview of the Program Models

The three program models presented in this section add a variety of services to an existing drug treatment program. The models assume a case management approach and 150 treatment slots per program. The tables present the following information for each program model:

- Functional tasks
- Staff needed to perform each task
- Time needed to complete each task
- Total number of direct and indirect service hours needed for 150 patient slots

The staffing levels presented in the tables allocate time for each task on a formula of 75 percent for direct service and 25 percent for indirect service. Indirect service time is computed as part of the total time needed to complete all tasks appropriately. For example, for each hour of staff work, 45 minutes is devoted to direct client service and 15 minutes is allotted for tasks such as charting and telephone calls. The staffing levels presented in the tables do not take into account tasks performed by administrative, managerial, and support personnel, such as a receptionist who answers the telephone and schedules appointments.

It is expected that there will be patient attrition for a variety of reasons. Staffing, patient scheduling, and screening will vary throughout the year due to the nature of the population and because of the need to screen or test for diseases more than once a year.

Overview of the Sample Budgets

The costs associated with the operation of each program model are presented in the sample budgets. Patients will be entering and leaving the program at different points in the treatment continuum; however, the sample budgets are based on a static patient population of 150 patient slots.

The sample budgets are based on these assumptions:

- The costs reflect fully operational programs at 150 patient slots.
- The tables identify a choice of professionals who could perform each task. For example, physicians and registered nurses are selected to provide the medical services. An intake worker and counselor are allotted to provide evaluation, counseling, and treatment planning services. In addition, salary ranges for social workers are used for the case manager positions.
- The wage rates are based on a limited survey. Actual salaries should be adjusted to prevailing wage rates for the geographic area.
- One full-time equivalent (FTE) position provides for 1,880 hours of service plus 80 hours of vacation and 40 hours of sick leave.
- The physician and nursing positions are paid on an hourly basis.
- The intake counselor and case manager positions are salaried.
- Laboratory costs per treatment slot are as follows:
 - Infectious disease screenings/tests - \$1,355
 - HIV-antibody testing - \$101
 - Combined HIV-antibody testing and infectious disease screenings/tests - \$1,456
- Laboratory charges are based on a limited national survey and on single-unit prices. Actual costs will vary by geographic area, particularly if volume discounts are available.
- Phlebotomy services are obtained from an outside laboratory rather than performed by a staff member. Costs are calculated at \$20 per hour.
- Clinical supplies are computed at \$20 per patient slot per year.
- A transportation allowance of \$20 per patient slot is included in the budgets to cover the cost of bus tokens or cab vouchers.
- Training and conference allowance costs are:
 - HIV counseling and testing program - \$500 per staff member
 - Infectious diseases screening program - \$250 per staff member
- The fringe benefit rate is calculated at 30 percent.
- An administrative overhead charge of 20 percent of total wages and fringe benefits is included in the budgets to provide for the costs of administrative supervision and support.
- The budgets do not include indirect costs necessary for the operation of a facility. Examples of indirect costs that should be considered part of an operating budget include:
 - space rental
 - utilities
 - telephone
 - cleaning
 - insurance
 - equipment purchase/rental and maintenance/ repairs
 - office supplies
 - depreciation
 - security services
- The budgets do not consider reimbursement issues. Before deciding to implement these guidelines, it may be advantageous to study Federal, State, local, and third-party reimbursement programs. Reimbursements from these sources may pay for part or all of the services offered by the program models.

Summary

The program models and sample budgets in this section provide examples of how to design and implement three different approaches to screening for infectious diseases in a drug treatment program. This information permits comparison between the costs of delivering separate or combined HIV/AIDS counseling and testing and infectious diseases screening programs. The economies of scale clearly indicate a cost advantage to a combined program. The HIV/< AIDS counseling and testing operation is a labor-driven program, while the infectious diseases screening program mainly involves costs for laboratory procedures. The combining of both HIV/AIDS counseling and testing and infectious diseases screening would allow for the greatest amount of programmatic and fiscal flexibility.

The number of patients in drug treatment programs with HIV/AIDS and infectious diseases continues to grow. At the present time, there is no reason to believe that this population will be decreasing in size. Given the strong correlation between HIV, infectious diseases, and chemical dependency, there is a need for drug treatment programs to consider enhancing their efforts by including counseling, testing, and screening services. The information provided in the guidelines, along with suggestions in this section for service design and implementation, staffing, and costing, are intended to guide States and local treatment programs in their efforts to provide services to this population.

Appendix F - Quality Assurance

Quality assurance (QA) procedures are employed by drug treatment programs to maintain or improve the level of care provided to patients and to control costs. These procedures ensure that the many components of a program work smoothly together and provide opportunities for representatives of all staff to come together to discuss interrelated issues. Deficiencies in program staffing, policy, function, and equipment are detected and corrected.

Quality Assurance Approach

Quality assurance is best accomplished through an interdisciplinary team approach. This team approach is put into practice by a QA committee composed of representatives from each of the disciplines present in the treatment program. Committee membership will vary based on the composition and size of the treatment program. Membership may include a program manager, medical director, counseling supervisor, clerical supervisor, and others.

Once a QA committee is constituted, review criteria must be identified for all aspects of the treatment program. These criteria permit an objective review of the quality of program services. Each criterion should have these characteristics:

- Be stated as a procedure or goal.
- Identify the individual/team of individuals who are responsible for its execution or completion.
- Indicate a standard, that is, the number of times the criterion is expected to be met.
- Identify exceptions that justify nonconformance.

The QA committee should develop and follow a quality assurance protocol. This protocol establishes the goals of the QA program, the frequency of committee meetings, and approved methods to conduct investigations, analyze findings, and deliver recommendations.

In addition, a mechanism should be established to receive and manage patient complaints about program services. Such a mechanism must accommodate significant patient feedback and provide for the thorough consideration and evaluation of each complaint.

Important Areas for Quality Assurance Monitoring

Experience has demonstrated that patients entering drug treatment programs need and benefit from a wide range of supportive services. Screening for infectious diseases is one of a number of critically needed services that can lead to enhanced overall health, a rejuvenated self-concept, and improved prospects for recovery from drug use. To provide comprehensive, high quality care, treatment staff are encouraged to carry out quality assurance monitoring.

A regular audit of patient records must be conducted. These audits should assess patient charts against established criteria to determine the appropriateness of diagnoses and treatment regimens, and the

completeness of all documentation. Also, nonclinical aspects of treatment programs should be reviewed and assessed by QA committee members.

The discussion below highlights major clinical and nonclinical areas for QA focus and provides the basis for criteria that are especially relevant to screening for infectious diseases. These, as well as other areas and criteria, can be added to existing quality assurance efforts or modified to meet individual program priorities and community circumstances.

Clinical Areas for QA Monitoring

History Taking

A complete and comprehensive history of the patient is essential. The process should produce information covering the patient's medical, drug use, psychosocial, and sexual history. This information sets the stage for the physical examination and followup care. Examples of quality assurance monitoring criteria include

- All histories are completed.
- Previous sexually transmitted disease, HIV, tuberculosis, hepatitis, and other infectious diseases test results and dates are documented.
- Pregnancy, or the likelihood of pregnancy, is documented.
- Allergies, and medications that are contraindicated, are documented.

Physical Examination

A thorough physical examination is needed to confirm information gathered from the patient and to reveal additional medical and service needs. The examination must assess the patient's immediate health status and provide the basis for prevention and treatment of infectious diseases. Examples of quality assurance monitoring criteria include

- Physical examination is completed.
- Laboratory tests are ordered.
- Appropriate tuberculosis skin test is offered. (Testing is required for the methadone-maintained patient.)
- HIV-screening test is offered.
- Serologic test for syphilis is offered. (Testing is required for the methadone-maintained patient.)
- Appropriate screening for viral hepatitis is offered when appropriate.
- Testing for hepatitis A and D is offered to appropriate patients.
- Testing for sexually transmitted diseases is offered when appropriate.

Laboratory Procedures

The Centers for Disease Control and Prevention suggests that for those programs that provide laboratory services, the quality of the procedures can be monitored regularly through the use of control studies. For example, a study of Gram stain versus culture correlation of male urethral discharges can be conducted.

Laboratory services should be provided by an approved laboratory that meets State certification requirements.

Treatment

Drug treatment programs offer a range of services in a variety of settings. A treatment plan is prepared for each patient and guides patient care. Screening for and treatment of infectious diseases should be part of the patient's treatment plan. Such services may be part of a treatment program's existing service capability, or

provided through the use of community-based referral networks. Examples of quality assurance monitoring criteria include

- Treatment plan is prepared and signed by appropriate staff.
- Patient chart is signed by clinician.
- Diagnosis correlates with laboratory and clinical findings.
- Treatment correlates with diagnosis.

Counseling

Patient counseling and educational services motivate patients to accept infectious disease testing, encourage follow through on prescribed treatment regimens, and support prevention initiatives. Patients learn how infectious diseases may threaten their recovery and are supported in their management of these diseases. Examples of quality assurance monitoring criteria include

- Pre- and post-test counseling is offered.
- Contact tracing and partner notification is facilitated and/or conducted.
- Risk-reduction counseling is provided.
- Retention in treatment interventions are implemented.
- Case management and followup services are offered.
- Confidentiality regulations and reporting requirements are discussed.

Referrals and Information Sharing

A key function of a QA program is to monitor the process of referral. Most treatment programs provide patients with referrals to other service organizations. Experience shows that merely making referrals for patients neither ensures that services are received nor guarantees the quality of the services that are delivered. Examples of quality assurance monitoring criteria are as follows:

- Referrals are documented, including reasons for the referrals and problems to be addressed.
- Results of referrals are documented, including patient evaluations, agreed-upon services, rejections and reasons for rejections, and evidence of other steps taken to provide services.
- Progress or termination of services, and the reason services were terminated, are documented.
- Appropriate accounting procedures are followed.

Reporting

Treatment programs that screen for infectious diseases play a particularly important role in surveillance reporting of infectious diseases. Diseases mandated reportable by State laws and regulations include many of those diagnosed in treatment populations. Treatment staff must be knowledgeable about and prepared to provide required data that is needed to safeguard public health. An example of quality assurance monitoring criteria is

- Required reporting of infectious diseases is done in accordance with State and local regulations.

Confidentiality Compliance

Each treatment program must ensure that internal policies and procedures comply with both Federal and State confidentiality and reporting regulations. Once compliance is ensured through the development of policies and staff training, a process of quality assurance monitoring should be developed to routinely review a sample of all program records. Examples of quality assurance monitoring criteria include

- The patient is informed of his or her right to confidentiality by program and referral agency staff.
- Written informed consent is on file whenever there are discussions concerning the patient with individuals or organizations outside the treatment facility.
- Written informed consent is time-limited, content-specific, person-to-person, signed, and witnessed.

Nonclinical Areas for QA Monitoring

Reviews of patient records reveal the quality of care being offered to individual patients and determine if treatment protocols are being followed and are adequate. Quality assurance activities must also address the nonclinical aspects of treatment programs that are critical for an effective infectious diseases screening component. Key nonclinical aspects for QA monitoring include interagency agreements, patient/staff interactions, environmental safety, and staff and community development.

Interagency Agreements

Many treatment programs rely on community-based medical facilities and laboratories to provide infectious diseases screening services and/or followup medical care. Patients may require other support services as well, such as legal, social, and financial assistance provided by organizations in the local community and by State and Federal organizations.

The referral process that connects the patient in treatment to needed services in the wider community requires good interagency collaboration and linkage. In order for interagency collaboration and linkage to be successful, there should be a written document that clearly delineates the responsibilities of the cooperating agencies. Interagency agreements, at a minimum, must have these characteristics:

- Describe the services to be provided by each agency.
- Describe the referral process to be used and the documentation requirements of each agency.
- Establish a time frame for the review and possible revision of the agreement.
- Examples of quality assurance monitoring criteria are as follows.
- The program referral conforms to all conditions of the appropriate interagency referral agreement.
- The referral agency adheres to all conditions of the interagency referral agreement.
- Agreed-upon services are provided in a timely manner.
- Referral documentation is complete.

Patient/Staff Interactions

Staff interactions with patients should be observed regularly - at least every 6 months. Monitoring of these interactions can identify staffing and workflow issues, communication problems, and other impediments to effective and comprehensive care needed by patients in treatment. Examples of quality assurance monitoring criteria include

- Number of patients seen by staff member meets program standards.
- Patient waiting times are within program standards.
- Staff skills are appropriate to patient needs.
- Staff demonstrate a nonjudgmental and culturally/ethnically sensitive manner when interacting with patients.

Environmental Safety

Semiannual safety audits are recommended by the Centers for Disease Control and Prevention for sexually transmitted disease clinics. Such regular audits can be beneficial for treatment programs as well. Criteria are needed to assess the effectiveness of procedures designed to ensure the safety of patients, staff, and the community. Examples of quality assurance monitoring criteria include

- Active cases of tuberculosis are isolated.
- Procedures are followed for the appropriate use of electrical equipment, including medical apparatus, heating and air conditioning units, lighting, and food preparation equipment.
- Chemicals, such as oxygen and cleaning solvents, and controlled substances, including methadone, are properly stored and secured.
- Evacuation procedures are in place in case of fire, civil disturbance, or natural disaster.
- Environmental security measures, such as proper ventilation, are in place to prevent contamination or the spread of infectious disease.

Staff and Community Interactions

Treatment staff implement treatment protocols and link the program to the broader community. As a result, staff must be knowledgeable about the origin, manifestations, prevention, and treatment of a number of infectious diseases common to the populations they serve. The following are examples of quality assurance monitoring criteria:

- Staff are offered training to enhance their cultural and ethnic competency.
- Staff are offered educational opportunities with respect to infectious diseases.
- Support networks for staff are encouraged.

Treatment Staff

Because treatment staff may be exposed to infectious diseases, they should be offered screening and treatment for specific infectious diseases. The following tests and precautions should be made available to treatment staff.

- Annual tuberculosis skin test; appropriate followup if indicated is recommended
- Hepatitis B test offered to direct-care medical staff
- Hepatitis B vaccine provided to direct-care medical staff with negative test results
- Preventive therapy offered to staff exposed to blood or body fluids from a patient infected with HIV

Implementing a Quality Assurance Program

A QA program to maintain and improve the quality of care provided by a treatment program is essentially an ongoing process. Establishing a QA committee begins the cycle and key elements of the process are summarized as follows:

- The QA committee selects review criteria that permit an objective review of the quality of patient services. Criteria are precise and have the four qualities that are identified above. The criteria are compiled into a QA plan for the program. [Figure 1](#) provides an example of a format for such a plan.
- A random sample of patient records is selected to ensure a true representation of program activities. Charts should be representative of the treatment population. A sample large enough to provide significant amounts of information about program operations is needed.
- QA committee members review the randomly selected charts and compare them to review criteria. Findings are noted on a quality assurance report form. A sample report form is presented by [figure 2](#).
- The QA committee meets regularly and members present any variations from the established standards that are found for each respective patient chart. Justification for any variation must be established by the QA committee or corrective action taken.
- The QA committee addresses each deficiency and determines the appropriate corrective action. Each deficiency is addressed and corrected by the responsible staff official (into whose area of responsibility the variation falls). The treatment program director has overall responsibility to ensure that corrective action is implemented. Followup action is recorded on a QA followup action form. An example of such a form as represented by [figure 3](#).

Deficiencies and corrective actions can be in the areas of knowledge, environment, or feedback. Deficiencies in knowledge may require further education of staff, such as in-service programs, further orientations, or demonstrations. Deficiencies in environment may require a restructuring to reduce interference, rearrangement of tasks or program flow, or provision of needed tools. Deficiencies in feedback may require discussions to clarify a function or task.

- The QA committee determines if the corrective action successfully solved the problem that produced the variation. Scrutiny of patient records during an established timeframe is required and results are discussed at subsequent QA committee meetings. If similar problems are noted, the committee must reevaluate the situation and new corrective action should be taken.
- QA committee findings may be presented in quarterly or other scheduled reports to agency boards, commissions, or other entities as directed.

Computer-Supported Quality Assurance

The QA process can be facilitated by computerized recordkeeping and use of management information systems. Computer capability can simplify the process and reduce the time required to gather, review, and analyze data and findings. For example, once review criteria and the key elements of each criterion are determined, computer printouts of relevant data from computerized records can be generated. Management information systems can correlate these data efficiently for subsequent analysis by committee members.

Appendix G - HIV/AIDS Prevention Bulletin

The HIV/AIDS Prevention Bulletin is unavailable in electronic form as part of TIP 6: Screening for Infectious Diseases Among Substance Abusers.

A copy of the entire TIP containing the HIV/AIDS Prevention Bulletin can be ordered from the National Clearinghouse of Drug and Alcohol Information (NCADI). The order number for TIP 6: Screening for Infectious Diseases Among Substance Abusers is BKD131. It is free and can be ordered from NCADI's electronic catalog at <http://ncadi.samhsa.gov/> or by calling 1-800-729-6686.

[Exhibits]

Table 1. Recommendations for the use of condoms

Table 1. Recommendations for the use of condoms

1. Use latex condoms because they offer greater protection against HIV and other viral STDs than natural membrane condoms.
2. Store condoms in a cool, dry place out of direct sunlight.
3. Do not use condoms in damaged packages or those that show obvious signs of age (for example, those that are brittle, sticky, or discolored).
4. Handle condoms with care to prevent puncture.
5. Put on the condom before any genital contact is made to prevent exposure to fluids that may contain infectious agents. Hold the tip of the condom and unroll it onto the erect penis, leaving space at the tip to collect semen. Make sure there is no air trapped in the tip of the condom.

6. Use only water-based lubricants. Petroleum- or oil-based lubricants such as petroleum jelly, cooking oils, shortening, and lotions should not be used because they weaken the latex and may cause the condom to break.
7. Use condoms containing spermicide, particularly those containing nonoxynol-9, to provide some additional protection against STDs. Vaginal use of spermicides along with condoms is likely to provide still greater protection.
8. Replace the condom immediately if it breaks. If ejaculation occurs after the condom breaks, the application of spermicide has been suggested. However, whether a post-ejaculation application of spermicide has protective value in reducing the risk of STD transmission is unknown.
9. Take care after the ejaculation that the condom does not slip off the penis before withdrawal. The base of the condom should be held throughout withdrawal. The penis should be withdrawn while still erect.
10. Never reuse a condom.

SOURCE: Centers for Disease Control. *Sexually Transmitted Diseases: Treatment Guidelines*. Atlanta, GA: U.S. Department of Health and Human Services, September 1989.

Table 1. CDC guidelines for preventing the transmission of tuberculosis in health care settings

Table 1. CDC guidelines for preventing the transmission of tuberculosis in health care settings

I. Early Identification and Treatment of Active TB Cases

The following guidelines will help health care personnel in the early identification and treatment of persons with active TB.

- A high index of suspicion for TB should be maintained to identify cases rapidly.
- Prompt, effective multidrug therapy should be initiated; this therapy should be based on clinical and drug-resistance surveillance data relative to the given geographical region and population demographics.

II. Preventing the Spread of Infection

The spread of infectious droplet nuclei needs to be prevented by source control methods and by the

reduction of microbial contamination of indoor air, using the following precautions.

- TB isolation precautions should be initiated immediately for all persons with suspected or confirmed active TB, since they may be infectious to others. Isolation precautions include placing the patient in a private room with negative pressure in relation to surrounding areas (i.e., air flow is from hallway into room and then to outdoors). The isolation room must have a minimum of six air exchanges per hour. Air from the room must be vented directly to the outside.
- To supplement proper ventilation, several other means to minimize exposure to TB should be considered. The use of disposable particulate respirators is recommended for staff members. These masks should be worn in clinic areas where aerosol treatments are given or sputum induction is done, as well as by hospital personnel in bronchoscopy suites and in patient isolation rooms. Patients should be instructed to cover their mouths when coughing or sneezing and to wear a mask when going out of isolation rooms.
- High-efficiency filtration systems may help reduce the risk of transmission, although their effectiveness has not been adequately evaluated in the clinical setting.
- Ultraviolet germicidal irradiation with UV-C in patient care areas, including outpatient clinics, may reduce the risk of transmission, although its effectiveness in the clinical setting has not been demonstrated.
- TB isolation precautions should be continued until the following conditions exist:
 - Three successive sputum samples obtained on different days are smear negative for AFB.
 - The patient has signs of clinical improvement.
 - The patient is receiving appropriate antituberculous therapy.
- Special respiratory and isolation precautions should be employed during any cough-inducing procedures (i.e., sputum induction; bronchoscopy; administration of aerosolized pentamidine to HIV-infected persons; nebulization treatment for asthma, emphysema; and when suctioning patients whether they are on a ventilator or not).

III. Surveillance for TB Transmission

Surveillance for TB transmission needs to be done to protect patients, health care workers, and visitors.

- Surveillance for TB infection should be maintained among health care workers by routine, periodic tuberculin skin testing every 6 to 12 months if there is no known exposure to a patient with active, untreated TB. Programs should recommend and follow up on appropriate preventive therapy for health care workers who meet the criteria for anti-TB prophylaxis. Immunocompromised health care workers, especially those with HIV/AIDS, may not convert their skin test and/or may be anergic. These workers need close medical followup.
- Ongoing surveillance for TB cases should be maintained among patients and health care workers.

- Contact investigation procedures need to be promptly initiated for any health care workers, patients, and visitors who are exposed to an untreated or ineffectively treated infectious TB patient who did not receive appropriate isolation and ongoing drug therapy. For infected contacts of infectious cases, appropriate anti-TB treatment or prophylaxis should be recommended. The initial therapeutic regimen should be based on the clinical history and on relevant, local drug-resistance surveillance data.

Table 1. Interpretation of tuberculosis skin test results

Table 1. Interpretation of tuberculosis skin test results

A reaction of 5 mm or greater is positive, regardless of age, in the following persons:

- Persons with known HIV infection
- Injection drug users whose HIV status is unknown
- Close contacts of newly diagnosed infectious tuberculosis cases, including health care workers
- Persons with chest radiographs showing fibrotic lesions

A reaction of 10 mm or greater induration is positive in the following:

- Foreign-born persons from high-prevalence countries
- Low-income populations, including high-risk minorities
- Injection drug users known to be HIV negative
- Residents of long-term care facilities (for example, nursing homes, correctional institutions)
- Persons with medical conditions that increase the risk of TB. These conditions include silicosis, diabetes mellitus, prolonged corticosteroid therapy, immunosuppressive therapy, hematologic and reticuloendothelial diseases, end-stage renal disease, intestinal bypass, postgastrectomy, chronic malabsorption syndrome, carcinomas of the oropharynx and upper gastrointestinal tract, and being 10 percent or more below ideal body weight.

Recent tuberculin skin test conversions(within a 2-year period) are considered positive: for those less than 35 years old, a 10 mm or more increase; for those 35 years and older, a 15 mm or more increase.

A tuberculin reaction of 15 mm or more is classified as positive in all other persons.

Table 2. Preventive treatment for tuberculosis

Table 2. Preventive treatment for tuberculosis
<ul style="list-style-type: none"> • INH (300 mg by mouth daily) for 6 to 12 months to prevent the development of active TB. • HIV-positive persons and persons at high risk for HIV, with unknown HIV status, should receive 12 months of INH. • For persons with a positive PPD after exposure to a known case of INH- resistant TB, rifampin (RIF) (600 mg by mouth daily) should be given for 6 to 12 months.

Table 3. Regimen options for the initial treatment of TB among children and adults

Table 3. Regimen options for the initial treatment of TB among children and adults	
TB Without HIV infection	TB With HIV Infection
<p>Option 1</p> <p>Administer daily INH, RIF, and PZA for 8 weeks followed by 16 weeks of INH and RIF daily or 2-3 times/week* in areas where the INH resistance rate is not documented to be less than 4%. EMB or SM should be added to the initial regimen until susceptibility to INH and RIF is demonstrated. Continue treatment for at least 6 months and 3 months beyond culture conversion. Consult a TB medical expert if the patient is symptomatic or smear or culture positive after 3 months.</p>	<p>Options 1, 2, or 3 can be used, but treatment regimens should continue for a total of 9 months and at least 6 months beyond culture conversion.</p>
<p>Option 2</p>	

<p>Administer daily INH, RIF, PZA, and SM or EMB for 2 weeks followed by 2 times/week* administration of the same drugs for 8 weeks (by DOT[§]), and subsequently, with 2 times/week administration of INH and RIF for 16 weeks (by DOT). Consult a TB medical expert if the patient is symptomatic or smear or culture positive after 3 months.</p>	
<p>Option 3</p> <p>Treat by DOT, 3 times/week* with INH, RIF, PZA, and EMB or SM for 6 months⁺. Consult a medical expert if the patient is symptomatic or smear or culture positive after 3 months.</p>	
<p>* All regimens administered 2 times/week or 3 times/week should be monitored by DOT for the duration of therapy.</p> <p>⁺ The strongest evidence from clinical trials is the effectiveness of all four drugs administered for the full 6 months. There is weaker evidence that SM can be discontinued after 4 months if the isolate is susceptible to all drugs. The evidence for stopping PZA before the end of 6 months is equivocal for the 3 times/week regimen, and there is no evidence on the effectiveness of this regimen with EMB for less than the full 6 months.</p> <p>[§] DOT=Directly observed therapy; INH=isoniazid; RIF=rifampin; PZA=pyrazinamide; EMB=ethambutol;</p>	

SM=streptomycin.

SOURCE: Centers for Disease Control and Prevention (1993).

Table 4. Dosage recommendations for the initial treatment of TB among children* and adults

Table 4. Dosage recommendations for the initial treatment of TB among children* and adults						
Dosage						
	Daily		2 times/week		3 times/week	
Drugs	Children	Adults	Children	Adults	Children	Adults
Isoniazid	10-20 mg/kg Max. 300 mg	5 mg/kg Max. 300 mg	20-40 mg/kg Max. 900 mg	15 mg/kg Max. 900 mg	20-40 mg/kg Max. 900 mg	15 mg/kg Max. 900 mg
Rifampin	10-20 mg/kg Max. 600 mg	10 mg/kg Max. 600 mg	10-20 mg/kg Max. 600 mg	10 mg/kg Max. 600 mg	10-20 mg/kg Max. 600 mg	10 mg/kg Max. 600 mg
Pyrazinamide	15-30 mg/kg Max. 2 gm	15-30 mg/kg Max. 2 gm	50-70 mg/kg Max. 4 gm	50-70 mg/kg Max. 4 gm	50-70 mg/kg Max. 3 gm	50-70 mg/kg Max. 3 gm
Ethambutol [§]	15-25 mg/kg Max. 2.5	15-25 mg/kg Max. 2.5	50 mg/kg Max. 2.5	50 mg/kg Max. 2.5	25-30 mg/kg Max. 2.5	25-30 mg/kg Max. 2.5

	gm	gm	gm	gm	gm	gm
Streptomycin	20-30 mg/kg	15 mg/kg	25-30 mg/kg	25-30 mg/kg	25-30 mg/kg	25-30 mg/kg
	Max. 1 gm	Max. 1 gm	Max. 1.5 gm	Max. 1.5 gm	Max. 1 gm	Max. 1 gm

* Children 12 years of age or less.

§ Ethambutol is generally not recommended

for children whose visual acuity cannot be monitored (< 6 years of age). However, ethambutol should be considered for all children with organisms resistant to other drugs, when susceptibility to ethambutol has been demonstrated, or susceptibility is likely.

SOURCE: Centers for Disease Control and Prevention (1993).

Table 1. Likelihood of infection with multidrug-resistant *Mycobacterium tuberculosis* among contacts thought to be newly infected

Table 1. Likelihood of infection with multidrug-resistant <i>Mycobacterium tuberculosis</i> among contacts thought to be newly infected*			
Infectiousness of the source MDR-TB⁺ case	Closeness and intensity of MDR-TB exposure	Contact's risk of exposure to drug-susceptible TB	Estimated likelihood of infection with multidrug-resistant <i>M. tuberculosis</i>[§]
+	+	-	High
+	-	-	High-intermediate
-	+	-	High-

			intermediate
-	-	-	Intermediate
+	+	+	Intermediate
+	-	+	Low-intermediate
-	+	+	Low-intermediate
-	-	+	Low

Key: (+) = high; (-) = low.

*Anergic contacts should be considered likely to be newly infected if there is evidence of contagion among contacts with comparable exposure.

⁺ MDR-TB = multidrug-resistant tuberculosis.

[§] Multidrug preventive therapy should be considered for persons in high, high-intermediate, and intermediate categories.

SOURCE: Centers for Disease Control, 1992*b*, p. 65.

Table 1. Characteristics of reported persons with AIDS diagnosed in 1992 in the United States

Table 1. Characteristics of reported persons with AIDS diagnosed in 1992 in the United States		
Category	No.	Percent

Sex:		
Male	40,461	85.9
Female	6,645	14.1
	47,106	100.0
Source of HIV exposure:		
Men having sex with men	23,936	50.8
Injection drug use	11,425	24.3
Injection drug use in combination with men having sex with men	2,429	5.2
Heterosexual contact	4,114	8.7
Perinatal	771	1.6
Other: no known risk factor, hemophilia, transfusion	<u>4,431</u>	<u>9.4</u>
	47,106	100.0
SOURCE: Centers for Disease Control and Prevention.		

Table 2. Behavioral and other risk indicators for HIV infection

Table 2. Behavioral and other risk indicators for HIV infection	
Behavioral risks for acquiring HIV infection by sexual transmission: <ul style="list-style-type: none"> • Unprotected oral, vaginal, or anal sex with anyone who has risk factors for HIV or with multiple partners • Unprotected sex with an infected person • A man having oral or anal 	Risk indicators for acquiring HIV infection by parenteral transmission: <ul style="list-style-type: none"> • A history of intravenous or injection drug usage, especially if needles or other drug paraphernalia have been shared • Recipient of blood or blood

<p>sex with another man</p> <ul style="list-style-type: none"> • History of exchanging sex for drugs or money • Presence of any sexually transmitted disease • History of incarceration, with sexual contact with a man • Having lived in, or having a sexual partner from, an area where HIV is endemic, such as the Caribbean basin - especially Haiti - and sub-Saharan Africa 	<p>product transfusions, especially between 1978 and 1985 (includes hemophiliacs, persons with sickle cell disease, and persons undergoing surgery for trauma or other reasons)</p> <ul style="list-style-type: none"> • Recipients of organ transplants prior to 1985 • Health care workers exposed to blood or bodily secretions from HIV-infected persons
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Table 3. Clinical manifestations often associated with HIV infection

Table 3. Clinical manifestations often associated with HIV infection

(The associated signs and symptoms are neither unique to HIV infection nor diagnostic of HIV infection. Findings of these signs or symptoms should alert the caregiver to the possibility of HIV.)

- Fever
- Unexplained weight loss; loss of appetite
- Night sweats
- Malaise, myalgias, arthralgias
- Cough, shortness of breath
- Swollen lymph nodes
- Visual changes, including visual field defects
- Recurrent or persistent sinusitis
- Abdominal pain, diarrhea
- Persistent, recurrent Candida vaginitis in women
- Cervical/vaginal dysplasia
- Neurologic conditions: headaches; difficulty in concentrating; short-term memory loss; pain in extremities, especially feet; photosensitivity; focal neurologic deficits (problems with balance, muscle strength, grasp)
- Easy bruising or abnormal bleeding associated with low platelets

Dermatologic conditions

- Folliculitis
- Molluscum contagiosum
- Condyloma acuminata (genital warts)
- Herpes simplex: oral, genital, rectal
- Rash
- Herpes zoster (shingles)
- Fungal dermatitis: tinea cruris (jock itch), tinea pedis (athlete's foot);

- fungal infection of nails, especially toenails
- Seborrheic dermatitis: especially of face, scalp
- Psoriasis
- Nonspecific pruritic rashes
- Drug eruption
- Kaposi's sarcoma

Oral cavity

- Oral lesions; periodontitis, gingivitis
- Thrush: Candida infection of tongue, oropharynx
- Kaposi's sarcoma: purple maculopapular lesions (especially hard palate)
- Hairy leukoplakia: plaques, especially lateral border of tongue
- Herpes simplex or zoster: vesicles or erosions

Table 4. CDC AIDS case definition for adults and adolescents

Table 4. CDC AIDS case definition for adults and adolescents

- Diagnosis based on CD4 count of less than 200 cells/mm³ or a CD4 percentage of less than 14, with laboratory confirmation of HIV infection.
- Diseases diagnosed definitively without confirmation of HIV in patients who do not have other causes of immunodeficiency
 - Candidiasis of the esophagus, trachea, bronchi, or lungs
 - Cryptococcosis, extrapulmonary
 - Cryptosporidium, greater than 1 month duration
 - Cytomegalovirus (CMV) infection of any organ except liver, spleen, or lymph nodes
 - Herpes simplex infection, mucocutaneous (greater than 1 month duration) or of the bronchi, lungs, or esophagus
 - Kaposi's sarcoma in patients aged less than 60 years
 - Primary CNS lymphoma in patients aged less than 60 years
 - *Mycobacterium avium* complex or *Mycobacterium kansasii*, disseminated/extrapulmonary
 - *Pneumocystis carinii* pneumonia
 - Progressive multifocal leukoencephalopathy
 - Toxoplasmosis of the brain
- Diseases diagnosed definitively with confirmation of HIV infection
 - Coccidioidomycosis, disseminated/extrapulmonary
 - Histoplasmosis, disseminated/extrapulmonary
 - Invasive cervical cancer
 - Isoporiasis diarrhea, greater than 1 month duration
 - Kaposi's sarcoma at any age
 - Primary CNS lymphoma at any age
 - Non-Hodgkin's lymphoma
 - Mycobacterial disease other than tuberculosis, disseminated/extrapulmonary
 - *Mycobacterium tuberculosis* infection, disseminated, pulmonary, extrapulmonary
 - *Salmonella septicemia*, recurrent
- Diseases diagnosed presumptively with confirmation of HIV infection
 - Candidiasis of the esophagus

- CMV retinitis
- Kaposi's sarcoma
- Disseminated mycobacterial disease
- *Pneumocystis carinii* pneumonia
- Toxoplasmosis of the brain
- HIV encephalopathy
- HIV wasting syndrome
- Recurrent pneumonia (more than one episode in a 1-year period)

Table 5. Antiretroviral drugs for treatment of HIV-infected adults

Table 5. Antiretroviral drugs for treatment of HIV-infected adults		
Drug	Dosage	Side Effects
AZT-zidovudine(Retrovir)	100 mg po 6 times per day	Anemia, leukopenia, thrombocytopenia, nausea, vomiting, headache, fatigue, myositis
ddC-zalcitabine(HIVID)	0.75 mg po t.i.d.	Peripheral neuropathy, oral ulcers, rash, pancreatitis, bone marrow suppression
ddI-didanosine(Videx)	≥ 60 kg: 200 mg po BID < 60 kg: 125 mg BID	Peripheral neuropathy, acute pancreatitis, hepatitis, headache, diarrhea

Table 6. Recommendations for prophylaxis against *Pneumocystis carinii* pneumonia for adults and adolescents with HIV infection

Table 6. Recommendations for prophylaxis against *Pneumocystis carinii* pneumonia for adults and adolescents with HIV infection

- Prophylaxis should be instituted with one of the following drugs and should be continued indefinitely.
- Because of the side effects of these drugs, the drug dosages may have to be changed or an alternative drug used.
- The drugs currently available for prophylaxis are trimethoprim/sulfamethoxazole (TMP/SMX), dapsone, pentamidine, or pyrimethamine-dapsone.
- The preferred regimen, if tolerated, is TMP/SMX daily.

Drug	Dosage (mg)	Side Effects
Trimethoprim/ sulfamethoxazole	160/800 mg orally every day or 3 days a week	Rash, fever, anemia, nausea, vomiting, low white blood cell count, elevated liver function tests, hepatitis, rare episodes of Stevens-Johnson syndrome.
Aerosolized pentamidine	300 mg aerosol (Respirgard) each month; 60 mg aerosol (Fisoneb) every 2 weeks	Bronchospasm, cough, wheezing, extrapulmonary PCP, pulmonary PCP with upper lobe disease, hypoglycemia.
Dapsone	100 mg orally once a day or twice a week	Check for G-6-P-D deficiency; contraindicated if G-6-P-D deficient. Rash, nausea, hemolytic anemia, and methemoglobinemia with or without G-6-P-D deficiency.
Pyrimethamine-dapsone	75 mg pyrimethamine	See side effects for dapsone;

	plus 200 mg of dapsone once a week	pyrimethamine: folic acid deficiency, leukopenia, anemia, pancytopenia, nausea, vomiting. Rarely headache, ataxia, tremors, seizures, fatigue, insomnia.
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Table 7. Recommended prophylaxis against *Mycobacterium avium* complex infection for adults and adolescents with HIV infection

Table 7. Recommended prophylaxis against <i>Mycobacterium avium</i> complex infection for adults and adolescents with HIV infection
<ul style="list-style-type: none"> • <i>Mycobacterium avium</i> complex (MAC) bacteremia or disseminated disease occurs frequently in HIV-infected persons with a CD4 count ≤ 100 cells/mm³. • As prophylaxis against MAC, consideration should be given to instituting lifelong treatment with rifabutin 150 mg orally twice a day. • Side effects of rifabutin include rash, diarrhea, low white blood cell count, low platelet count, increased liver enzymes, especially SGOT. • Drug interactions: rifabutin may alter the metabolism of oral contraceptives, methadone, phenytoin (Dilantin), and AZT. • Women using oral contraception as a form of birth control should be advised to also use barrier contraception while on rifabutin and be advised of the risk of becoming pregnant. • Persons on methadone maintenance may need to have their methadone dosage adjusted to prevent withdrawal symptoms.

Table 8. Centers for Disease Control and Prevention signs and symptoms of serious opportunistic diseases

Table 8. Centers for Disease Control and Prevention signs and symptoms of serious opportunistic diseases
<ul style="list-style-type: none"> • <i>General</i>: fever and/or weight loss • <i>Neurologic</i>: peripheral neuropathy, altered level of consciousness; cognitive, motor, or behavioral impairments; intractable headache; visual disturbances; focal neurological deficits • <i>Dermatologic</i>: multidermatomal herpes zoster, reddish purple or dark pigmented skin macules or nodules, papules or skin or mucous membranes

- *Respiratory*: persistent dry cough not due to smoking, shortness of breath
- *Gastrointestinal*: difficult or painful swallowing, persistent watery diarrhea, abdominal cramping

Table 1. Behavioral risk factors

Table 1. Behavioral risk factors	
	<ul style="list-style-type: none"> • Syphilis is primarily transmitted through contact with an infectious lesion, usually during sexual intercourse. • Syphilis can be acquired by kissing or touching a person who has infectious lesions on the lips, breast, genitals or rectum, or in the oral cavity. • Syphilis may be transmitted by the sharing of needles for injection drug use. • The fetus of an infected mother can contract syphilis. Syphilis can also be transmitted in breast milk. • Persons using crack cocaine, especially those engaging in sexual activity in crack houses, are at highest risk. • Persons with multiple sexual partners, especially in areas where illegal drug usage is endemic, are at an increased risk for acquiring syphilis. • Men or women exchanging sex for drugs, money, or shelter are at risk for syphilis infection.

Table 2. Percentage of patients with positive serologic test results in untreated syphilis

Table 2. Percentage of patients with positive serologic test results in untreated syphilis				
	Stage of Disease			
	Primary	Secondary	Latent	Late
VDRL	59--87	100	73--91	37--94
FTA--ABS	86--100	99--100	96--99	96--100
MHA-TP	64--87	96--100	96--100	94--100*
*Includes some patients whose treatment status is unknown				
SOURCE: Jaffe, H.W., and Musher, D.M. Management of				

the reactive syphilis serology. In: Holmes, K.; Mardh, P.; Sparling, P.; Wiesner, P.; Cates, Jr., W.; Lemon, S.; and Stamm, W. *Sexually Transmitted Diseases*. 2d. ed. New York: McGraw-Hill, 1990, p. 935. Copyright 1990. Reprinted with permission of McGraw-Hill, Inc.

Table 3. Recommended treatment regimen for early syphilis

Table 3. Recommended treatment regimen for early syphilis
Recommended regimen: <ul style="list-style-type: none">• Benzathine penicillin G, 2.4 million units (mu) intramuscularly (IM) (1.2 mu in each buttock) - one treatment Treatment options for the penicillin-allergic patient (nonpregnant): <ul style="list-style-type: none">• Doxycycline 100 mg by mouth twice daily for 14 days or <ul style="list-style-type: none">• Tetracycline 500 mg by mouth four times daily for 14 days

Table 4. Recommended treatment regimen for late latent syphilis

Table 4. Recommended treatment regimen for late latent syphilis
Recommended regimen: <ul style="list-style-type: none">• Benzathine penicillin G: 2.4 million units IM (1.2 mu in each buttock) given weekly for 3 weeks Treatment for the penicillin-allergic patient who has no evidence of CNS syphilis and is not pregnant: <ul style="list-style-type: none">• Doxycycline 100 mg by mouth twice daily for 28 days

Table 5. Recommended treatment regimen for neurosyphilis

Table 5. Recommended treatment regimen for

neurosyphilis
<ul style="list-style-type: none"> Aqueous penicillin G, 24 million units per day intravenously for 10 days; followed by benzathine penicillin G, 2.4 million units intramuscularly weekly for 3 weeks <p>or</p> <ul style="list-style-type: none"> Procaine penicillin G, 2.4 million units per day intramuscularly for 10 days; plus probenecid, 500 mg orally four times a day (every 6 hours) for 10 days; followed by benzathine penicillin G, 2.4 million units intramuscularly weekly for 3 weeks <p>Treatment for the penicillin-allergic patient:</p> <ul style="list-style-type: none"> Desensitization to penicillin in an outpatient or hospital setting with expert advice

Table 6. Recommended treatment regimens for HIV-infected persons

Table 6. Recommended treatment regimens for HIV-infected persons
<ul style="list-style-type: none"> Penicillin is the recommended treatment for all stages of syphilis For the penicillin allergic patient, desensitization to penicillin is recommended <p>Treatment of primary and secondary syphilis</p> <ul style="list-style-type: none"> Benzathine penicillin G, 2.4 million units (mu) intramuscularly (IM) once <p>Treatment of early or late latent syphilis</p> <ul style="list-style-type: none"> CSF examination before treatment For patient with normal CSF: Benzathine penicillin G, 7.2 mu (as 3 weekly doses of 2.4 mu each week) For patient with CSF consistent with neurosyphilis (i.e., CSF leukocyte count greater than 5 WBC/mm³; elevated CSF protein; reactive CSF-VDRL; or reactive CSF FTA-ABS) see table 5 for treatment recommendations for neurosyphilis

Table 1. Guidelines for health care providers exposed to bloodborne pathogens

Table 1. Guidelines for health care providers
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exposed to bloodborne pathogens

In accordance with OSHA rules and regulations, the following rules apply for health care workers doing phlebotomy:

1. Disposable (single use) gloves must be made available to all health care workers.
2. Contaminated needles and other sharps shall not be recapped or removed, unless no alternative is feasible.
3. Any recapping or needle removal must be done with a mechanical device or one-handed technique.
4. Any contaminated needle or sharp that is being disposed of must be placed in an appropriate, approved disposal that is readily available.
5. Gloves shall be worn when it is anticipated that the employee may have contact with blood, other potentially infectious materials, mucous membranes, and nonintact skin; when performing vascular access procedures including phlebotomy; and when handling or touching contaminated items or surfaces.
6. Employers must implement and enforce the OSHA Rules and Regulations (Part 1910 of title 29 CFR, Section 1910.1030 - Bloodborne Pathogens).

Table 2. Risk factors for acquisition of viral hepatitis B

Table 2. Risk factors for acquisition of viral hepatitis B

- Multiple sexual partners (heterosexuals, homosexuals, or bisexuals)
- Use of injection drugs, especially with multiple partners
- Household contacts of HBV carriers
- Use or sharing of contaminated needles, syringes, and other drug paraphernalia
- Hemodialysis patients
- Perinatal exposure to HBsAg-positive mother
- Workers at occupational risk, especially health care workers and public safety workers exposed to blood in the workplace
- Inmates of long-term correctional facilities
- Patients and staff members in institutions for the developmentally disabled
- Persons born in or having resided in parts of the world where hepatitis B infections are endemic, such as Southeast Asia, Africa, the Republic of China, the People's Republic of China, the Amazon Basin, and Alaska (among Alaskan Natives)

Table 3. Symptoms of acute hepatitis

Table 3. Symptoms of acute hepatitis

- Fever - absent or mild - occurring from 2 to 7 days before the onset

of jaundice

- Headache, malaise, chills
- Vague abdominal discomfort, especially in the right upper quadrant
- Nausea and occasional vomiting; diarrhea
- Rash - erythematous, maculopapular
- Anorexia - loss of appetite with an aversion to food and tobacco
- Pruritus
- Arthralgias/arthritis
- Dark urine (tea-colored) and light- or clay-colored stools
- Scleral, mucous membrane, and cutaneous icterus
- Enlarged tender liver
- Palpable spleen
- Lymphadenopathy, especially posterior cervical nodes

Table 4. Hepatitis B serology and correlations with stage of infection

Table 4. Hepatitis B serology and correlations with stage of infection								
		Serology						
Time	Stage	HBsAg	Anti-HBs	Anti-HBc IgM	Anti-HBc IgG	HbeAg	Anti-HBe	Immunity/ Infectivity
6 wks to 6 mos	Incubation period	-	-	-	-	-	-	Not infectious
1 to 2 wks	Late incubation	++	-	-	-	+ or -	-	Infectious
2 to 4 wks	Acute	++	-	++	++	++	-	Infectious
Up to 6 mos	HBsAg-negative Acute HBV	-	-	++	++	-	-	Potentially infectious
6 mos	HBV in recent	-	++	+ or -	++	-	++	Infectivity low

to years	past							
	HBV in distant past	-	+ or -	-	+ or -	-	-	Immune
	Chronic HBV	++	-	+ or -	+++	++	-	Infectious
	Healthy HBsAg carrier	++	-	+ or -	+++	-	++	Infectious

Table 5. Recommended doses of HB vaccines by group

Table 5. Recommended doses of HB vaccines by group				
	Recombivax-HB		Energix-B	
Group	Dose (mg)	(mL)	Dose (mg)	(mL)
Children and adolescents 11--19 years	5	(0.5)	20	(1.0)
Adults \leq 20 years	10	(1.0)	20	(1.0)
Dialysis patients, HIV-infected persons, other immunocompromised persons	40	(1.0)	40	(2.0)

Table 6. CDC suggestions for interrupted hepatitis B vaccine series

Table 6. CDC suggestions for interrupted hepatitis B vaccine series
For persons who do not complete the three- or four-dose

series HB vaccine, the following suggestions are made by the CDC:

- If the series is interrupted after the first dose, the second dose should be given as soon as possible.
- The second and third doses should be separated by an interval of at least 2 months.
- If only the third dose is delayed, it should be given when convenient.

Table 7. CDC recommendations for hepatitis B prophylaxis following percutaneous exposure

Table 7. CDC recommendations for hepatitis B prophylaxis following percutaneous exposure

Prophylaxis of sex partners of persons with HBV infections should include the following:

1. Test exposed person for anti-HBc.
2. If the test is negative, the following are recommended:
 - If the sex partner has acute HBV infection, the exposed person should receive a single dose of HBIG (0.06 mL/kg) and the first dose of the hepatitis B vaccine. The vaccine may be given simultaneously with HBIG but not at the same injection site.
 - If the sex partner is a chronic carrier (HBsAg positive), the exposed person should receive the hepatitis B vaccine series.

Prophylaxis of household contacts of persons with acute hepatitis B infection should include the following:

1. An infant less than 12 months of age exposed to a primary caregiver with acute HBV should be given HBIG (0.5 mL) and hepatitis B vaccine.
2. Household contacts other than exposed infants should receive HBIG (0.06 mL/kg) and hepatitis B vaccine only if they have had potential or known exposure to the blood of the actively infected person (i.e., sharing toothbrushes or razors).
3. If the person with acute HBV infection becomes a chronic carrier (HBsAg positive after 6 months), all household contacts should receive HB vaccine.

Table 8. CDC guidelines for vaccinating infants

Table 8. CDC guidelines for vaccinating infants

Current CDC guidelines call for all infants to be vaccinated

for HBV, regardless of the HBsAg status of the mother. Any infant born to a mother known to be HBsAg positive should begin the vaccine series and receive hepatitis B immune globulin within 12 hours of delivery. If the HBsAg status of the mother is unknown at the time of delivery, the infant should receive the initial vaccine dose within 12 hours of birth. If the mother is found to be HBsAg positive, HBIG should be administered as soon as possible and not later than 1 week after birth.

Table 1. Risk factors

Table 1. Risk factors
<ul style="list-style-type: none"> • Injection drug use, especially sharing of contaminated needles, syringes, and other drug paraphernalia • Injection drug use with multiple partners • Unprotected sexual activity among men who have sex with other men, with IDUs, with prostitutes, and among heterosexuals with multiple sexual partners • Perinatal transmission from an HCV-infected mother to her infant • Health care workers exposed via needlesticks • Persons receiving hemodialysis for renal failure • Recipients of blood or blood products, especially those receiving transfusions prior to 1990

Table 2. Symptoms of acute hepatitis C

Table 2. Symptoms of acute hepatitis C
<p>Symptoms of acute HCV infection, <i>if present</i>, may include the following:</p> <ul style="list-style-type: none"> • A flulike illness • Fatigue, malaise, fever, chills • Anorexia, loss of appetite • Nausea and occasional vomiting • Dark urine (the color of cola drinks) • Vague abdominal discomfort, especially in the right upper quadrant • Jaundice, with yellow eyes, skin, and mucous membranes

Table 1. Recommended treatment regimen for uncomplicated urethral, cervical, rectal, or pharyngeal gonorrhea

Table 1. Recommended treatment regimen for

uncomplicated urethral, cervical, rectal, or pharyngeal gonorrhea

- Ceftriaxone 125 mg intramuscularly in a single dose or one of the following:
- Cefixime 400 mg orally in a single dose or
- Ofloxacin 400 mg orally in a single dose or
- Ciprofloxacin 500 mg orally in a single dose or
- Spectinomycin 2.0 gm intramuscularly in a single dose

For patients treated with these regimens, routine followup culture is not necessary. The patients should be reevaluated after 1 to 2 months for possible treatment failure or reinfection.

Concurrent treatment for chlamydia: doxycycline 100 mg orally two times a day for 7 days or azithromycin 1 g orally once.

Table 2. Recommended treatment for gonorrhea in pregnancy

Table 2. Recommended treatment for gonorrhea in pregnancy

Recommended treatment regimen:

- Ceftriaxone 125 mg intramuscularly in a single dose

plus

- Treatment for chlamydia with erythromycin base 500 mg orally four times a day for 7 days.
- Followup cervical and rectal cultures should be obtained 4 to 7 days after the initial treatment.
- For pregnant women allergic to ceftriaxone, spectinomycin 2 g IM once is recommended along with erythromycin for chlamydia.

Ciprofloxacin, ofloxacin, and other fluoroquinolones, as well as tetracycline and doxycycline, are contraindicated in pregnancy.

Table 1. Treatment regimens for chlamydia for nonpregnant patients

Table 1. Treatment regimens for chlamydia for

nonpregnant patients
<p>Recommended regimen:</p> <ul style="list-style-type: none"> • Doxycycline 100 mg orally two times a day for 7 days <p>or</p> <ul style="list-style-type: none"> • Azithromycin 1 g once orally <p>Alternative regimens:</p> <ul style="list-style-type: none"> • Ofloxacin 300 mg orally two times a day for 7 days <p>or</p> <ul style="list-style-type: none"> • Erythromycin base 500 mg orally four times a day for 7 days

Table 2. Recommended treatment for chlamydia in pregnancy

Table 2. Recommended treatment for chlamydia in pregnancy
<p>Recommended regimen:</p> <ul style="list-style-type: none"> • Erythromycin base 500 mg orally four times a day for 7 days <p>or</p> <ul style="list-style-type: none"> • Erythromycin base 250 mg orally four times a day for 14 days or • Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days <p>or</p> <ul style="list-style-type: none"> • Erythromycin ethylsuccinate 400 mg orally four times a day for 14 days <p>Note: Tetracycline, doxycycline, and the quinolones, including ofloxacin, should not be given during pregnancy. Erythromycin estolate is contraindicated during pregnancy because of drug-related hepatotoxicity. In women of childbearing potential, a pregnancy test should be done prior to prescribing these drugs. The safety and efficacy of azithromycin for pregnant and lactating women has not</p>

been established.

If erythromycin is not tolerated, an effective regimen may be:

- Amoxicillin 500 mg orally three times a day for 7 days

Followup cultures to test for cure should be done on all pregnant women 3 or more weeks after therapy, especially if the amoxicillin regimen is used.

Table 1. Recommended treatment regimens for herpes simplex

Table 1. Recommended treatment regimens for herpes simplex
First Clinical Episode <ul style="list-style-type: none">• Acyclovir (Zovirax) 200 mg orally five times a day for 7 to 10 days or until clinical resolution occurs.• Herpes proctitis or severe infection may require higher doses of oral or intravenous acyclovir.• Topical acyclovir is not effective and should not be prescribed.
Recurrent Episodes <ul style="list-style-type: none">• Persons with severe recurrent episodes of herpes may benefit from treatment with acyclovir if the drug is begun during the prodrome or within 2 days of the onset of lesions.• For persons with frequent recurrences of herpes infections (more than six per year), suppressive treatment with acyclovir 400 mg orally twice a day or 200 mg orally two to five times a day for most persons will decrease the frequency and severity of recurrent genital herpes.• For persons with chronic and refractory herpes who were HIV negative in the past or whose HIV status is unknown, HIV testing should be done, as they may be HIV infected.• After 1 year of suppressive therapy, the acyclovir should be discontinued, since some persons have no recurrences or have only rare and mild recurrences of HSV infection.
For HIV-Infected Persons <ul style="list-style-type: none">• HIV-infected persons may not respond as well to suppressive treatment for recurrent episodes of genital herpes as persons who are not HIV infected. HIV-infected persons may need more prolonged treatment and require higher or increased doses of acyclovir to control the herpes infection.

- HIV-infected persons who fail to respond to acyclovir may have developed acyclovir-resistant herpes, and they must be referred to a physician or hospital.
- Acyclovir-resistant herpes requires treatment with intravenous foscarnet.

Table 1. Recommended treatment regimens for chancroid

Table 1. Recommended treatment regimens for chancroid
<p>Recommended regimen:</p> <ul style="list-style-type: none"> • Azithromycin, 1 g orally in a single dose or • Ceftriaxone 250 mg intramuscularly in a single dose or • Erythromycin base 500 mg orally four times a day for 7 days <p>Alternative regimens include:</p> <ul style="list-style-type: none"> • Amoxicillin 500 mg plus clavulanic acid 125 mg three times a day for 7 days <p>or</p> <ul style="list-style-type: none"> • Ciprofloxacin 500 mg orally, twice a day for 3 days <p>Note: Ciprofloxacin is contraindicated during pregnancy. Patients 17 years of age and under should not receive ciprofloxacin.</p>

Table 1. Model A - Tasks, staffing, and time for HIV-antibody counseling and testing

Table 1. Model A - Tasks, staffing, and time for HIV-antibody counseling and testing			
Task	Staff¹	Time per task (per client)	Total hours² 150 Slots
Evaluation	Intake worker Counselor Intern	2 hours	400

Physical and followup	Physician Physician's assistant Nurse practitioner	45 minutes	150
Assist physician	Nurse	45 minutes	150
Lab work--routine	Phlebotomist or refer to outside laboratory	20 minutes	67
Unable to obtain sample	Refer to outside physician, outside clinic/hospital for femoral stick		
Counseling and testing for HIV/AIDS	Counselor Pre-test counseling Post-test counseling	30 minutes 45 minutes	100 150
Treatment planning	Counselor	30 minutes	100
Counseling, education, treatment planning, and case management	Case manager Nurse Health educator	47 hours(5 FTEs per 150 patients)	9,400

¹ All staff trained and experienced in drug treatment and HIV/AIDS.

² Consists of a time--allocation formula of 75 percent for

direct services and 25 percent for indirect services.

Table 1a. Model A - HIV-antibody counseling and testing program sample budget for 150 treatment slots

Table 1a. Model A - HIV-antibody counseling and testing program sample budget for 150 treatment slots				
Personnel Costs				
Position	Hours required	Full-time equivalents needed	Compensation	Total cost
Intake/Counselor	750	0.40	\$25,000 per year	\$ 10,000
Case manager	9,400	5.00	\$30,000 per year	150,000
Physician	150	0.08	\$100 per hour	15,000
Nurse/Nurse practitioner	150	0.08	\$20 per hour	3,000
Total Wages				\$178,000
Fringe Benefits @ 30% of wages				53,400
Total Personnel Costs				\$231,400
Other Costs				Cost
Laboratory (150 patients @ \$101)				\$15,150
Phlebotomy (67 hours for a phlebotomist @ \$20/hr.)				1,340
Clinical Supplies (150 patients @ \$20)				3,000
Publications				1,000

Training and Conferences (8 staff @ \$500)	3,000
Transportation (150 patients @ \$20)	3,000
Administrative Support (20% of wages + fringes)	46,280
Total Other Cost	\$73,770
Total Personnel and Other Costs	\$305,170

Table 2. Model B - Tasks, staffing, and time for screening for infectious diseases (not including HIV)

Table 2. Model B - Tasks, staffing, and time for screening for infectious diseases (not including HIV)			
Task	Staff¹	Time per task (per client)	Total hours² 150 Slots
Evaluation	Intake worker Counselor Intern	2 hours	400
Physical and followup	Physician Physician's assistant Nurse practitioner	30 to 45 minutes per client, 4 to 6 clients per 8 hours	150
Assist physician	Nurse	45 minutes	150
Lab work--routine	Phlebotomist or refer to outside laboratory	20 minutes	67
Unable to obtain sample	Refer to outside		

due to lack of veins	physician, outside clinic/hospital for femoral stick		
Counseling, education, treatment planning, and case management	Case manager Nurse Health educator	19 hours (2 FTEs per 150 patients)	3,760
¹ All staff trained and experienced in drug treatment and HIV/AIDS. ² Consists of a time-allocation formula of 75 percent for direct services and 25 percent for indirect services.			

Table 2a. Model B - Infectious diseases screening program sample budget for 150 treatment slots

Table 2a. Model B - Infectious diseases screening program sample budget for 150 treatment slots				
Personnel Costs				
Position	Hours required	Full-time equivalents needed	Compensation	Total cost
Intake/Evaluation	400	0.25	\$25,000 per year	\$ 6,250
Case manager	3,760	2.00	\$30,000 per year	60,000
Physician	150	0.08	\$100 per hour	15,000
Nurse/Nurse	150	0.08	\$20 per hour	<u>3,000</u>

practitioner				
Total Wages				\$84,250
Fringe Benefits @ 30% of wages				25,275
Total Personnel Costs				\$109,525
Other Costs				Cost
Laboratory (150 patients @ \$1,355)				\$203,250
Phlebotomy (67 hours for a phlebotomist @ \$20/hr.)				1,340
Clinical Supplies (150 patients @ \$20)				3,000
Publications				500
Training and Conferences (8 staff @ \$500)				1,250
Transportation (150 patients @ \$20)				3,000
Administrative Support (20% of wages + fringes)				21,905
Total Other Cost				\$234,245
Total Personnel and Other Costs				\$343,770

Table 3. Model C - Tasks, staffing, and time for HIV-antibody counseling and testing and screening for other infectious diseases

Table 3. Model C - Tasks, staffing, and time for HIV-antibody counseling and testing and screening for other infectious diseases			
Task	Staff¹	Time per task (per client)	Total hours² 150 Slots
Evaluation	Intake worker Counselor	150 minutes	500

	Intern		
Physical and followup	Physician Physician's assistant Nurse practitioner	60 minutes	200
Assist physician	Nurse	60 minutes	200
Lab work-- routine	Phlebotomist or refer to outside laboratory	30 minutes	100
Unable to obtain sample due to lack of veins	Refer to outside physician, outside clinic/hospital for femoral stick		
Counseling, education, treatment planning, and case management	Case manager Nurse Health educator	66 hours (2 FTEs per 150 patients)	13,160
¹ All staff trained and experienced in drug treatment and HIV/AIDS. ² Consists of a time-allocation formula of 75 percent for direct services and 25 percent for indirect services.			

Table 3a. Model C - Tasks, staffing, and time for HIV-antibody counseling and testing and screening for other infectious diseases

Table 3a. Model C - Tasks, staffing, and time for HIV-antibody counseling and testing and screening for other infectious

diseases				
Personnel Costs				
Position	Hours required	Full-time equivalents needed	Compensation	Total cost
Intake/Counselor	850	0.50	\$25,000 per year	\$ 12,500
Case manager	13,160	7.00	\$30,000 per year	210,000
Physician	200	0.11	\$100 per hour	20,000
Nurse/Nurse practitioner	200	0.11	\$20 per hour	<u>4,000</u>
Total Wages				\$246,500
Fringe Benefits @ 30% of wages				73,950
Total Personnel Costs				\$320,450
Other Costs				Cost
Laboratory (150 patients @ \$1,456)				\$218,400
Phlebotomy (100 hours for a phlebotomist @ \$20/hr.)				2,000
Clinical Supplies (150 patients @ \$20)				3,000
Publications				1,000
Training and Conferences (10 staff @ \$500)				5,000
Transportation (150 patients @ \$20)				3,000
Administrative Support (20% of wages + fringes)				64,090

Total Other Cost	\$296,490
Total Personnel and Other Costs	\$616,940

Table 4. Medicaid reimbursement rates for medical procedures

Table 4. Medicaid reimbursement rates for medical procedures		
<i>Physicians' Current Procedural Terminology code</i>	Name of procedure by category	Medicaid payment
Radiology		
71010	Chest x-ray	\$ 9.76
Chemistry		
80004	Electrolytes	8.43
80006	Chem 6	8.98
80009	Liver profile	11.09
80012	Chem 12	10.80
80018	Chem 18 (17--18 tests)	14.33
80019	Chem 20 (a generic for more than 19 tests)	15.04
84450	AST (SGOT)	5.91
84460	ALT (SGPT)	5.83
80070	Thyroid panel	16.19
82150	Amylase	8.57

83690	Lipase	8.22
82947	Glucose tests	5.23
82952	Glucose challenge	7.01
83705	Lipids, fractionated: cholesterol, triglycerides, and phospholipids	15.28
86244	Alpha-fetoprotein	18.09
Hematology		
83020	Hemoglobin, electrophoresis	12.54
83053	Sickle cell	6.93
85024	CBC--complete blood count	10.98
86082	ABO type and Rh factor	6.72
88180	Total CD4 count; CD4:CD8 (T4:T8) ratio	45.76
Toxicology		
82055	Blood alcohol	15.56
82065	Alcohol (Blood or urine)	13.33
82660	Urine drug screen panel	14.49
83645	Lead screening, blood	8.61
82840	Methadone	8.95
Urinalysis		
81000	Routine urinalysis, including microscopic examination	\$ 4.64
Pathology		

47120	Liver biopsy	484.62
88150	Papanicolaou smear	7.18
88312	Special stains for tissue scrapping for herpes virus or tissue biopsy	13.73
Microbiology		
87040	Bacterial blood culture	14.12
87087	Urine culture	6.49
87116	Culture, tubercle or other acid-fast bacilli (e.g., TB, AFB, mycobacteria); any source, isolation only	8.89
87118	Culture, mycobacteria, definitive identification of each organism	14.27
87205	Smear, with interpretation; routine stain for bacteria, fungi, or cell types (e.g., cervical smear-gonorrhea)	5.43
Gonorrhea		
87070	Neisseria gonorrhea culture	11.93
87163	Culture of discharge from mucosal surfaces in Thayer-Martin (chocolate agar supplemented with antibiotics)	14.21
Serology		
82784	Immunoglobulin G, A, M, D	14.50
84231	Solid-phase radioimmunoassay (RIA)	18.12

86016	Antibody screen	8.89
86255	Fluorescent antibody (e.g., chlamydia, herpes screening)	12.81
86317	Immunoassay for infectious agent antigen or antibody (e.g., chlamydia)	15.73
86320	Serum gammaglobulin levels	27.09
86403	Particle agglutination rapid test (e.g., rubella antibody; cryptococcal antigen)	13.77
88346	Immunofluorescent stain (e.g., chlamydia DFA or herpes DFA)	\$33.47
HIV		
86312	HIV-EIA (enzyme immune assay)	13.06
86314	Confirmatory test for HIV (Western blot)	27.93
Syphilis		
86592	RPR--syphilis (qualitative)	4.70
86593	VDRL--venereal disease reference laboratory (quantitative)	5.84
86650	FTA-ABS	14.44
Tuberculosis		
86580	Tuberculosis intradermal skin test (Mantoux text)	6.49
Hepatitis		
80059	Hepatitis profile	42.74

Hepatitis B		
86287	Hepatitis B surface antigen screen	13.89
86289	Anti-hepatitis B core antibody	16.48
86291	HBsAb--hepatitis B surface antibody	14.83
Hepatitis A		
86299	Hepatitis A (IgM Anti-HAV)	14.92
Hepatitis B vaccine		
90731	Recombivax HB (MSD) vaccine	34.47
90742	Energix-B (SK Biologicals)	37.50
<p>SOURCE: <i>Special analysis for CSAT done by the Division of Medicaid Statistics, Office of Program Systems, Bureau of Data Management and Strategy, Health Care Financing Administration. Data are from the period July<196>September 1991. The data were obtained from the individual claims data supplied by State Medicaid agencies to the Medicaid Statistical Information System at the Health Care Financing Administration. The participating States were Alaska, Alabama, California, Delaware, Georgia, Indiana, Iowa, Kansas, Kentucky, Maine, Missouri, Montana, New Jersey, North Dakota, New Hampshire, Utah, Vermont, Washington, Wisconsin, and Wyoming.</i></p>		

Figure 1: Sample quality assurance plan

Figure 1: Sample quality assurance plan				
AREA _____				
Criteria	Standard	Exceptions	QA method	Responsible person

Chart signed by physician	100%	None	Monthly review of 100% of charts	Nurse Supervisor

Figure 2: Sample quality assurance report form

Figure 2: Sample quality assurance report form				
AREA _____				
Date _____				
Criteria	Standard	Compliance		Comment
Chart signed by examining physician	100% of all charts signed by examining physician	Yes	No	

Figure 3: Sample quality assurance followup action form

Figure 3: Sample quality assurance followup action form				
AREA _____				
Problem description	Criteria	Followup date/status	Followup date/status	Followup date/status
Chart not signed by examining physician	100% of all charts signed by examining physician	1/4/93: chart signed on 12/27/92	2/4/93: chart signed on 1/26/93	

